BMJ Open

RESTORE – Cognitive Functional Therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain: study protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031133
Article Type:	Protocol
Date Submitted by the Author:	18-Apr-2019
Complete List of Authors:	Kent, Peter; Curtin University, School of Physiotherapy and Exercise Science; University of Southern Denmark, Department of Sports Science and Clinical Biomechanics O'Sullivan, P; Curtin University, School of Physiotherapy and Exercise Science Smith, Anne; Curtin University, School of Physiotherapy Haines, Terrence; Monash University, Faculty of Medicine, Nursing & Health Science Campbell, Amity; Curtin University, Physiotherapy and Exercise Science McGregor, Alison; Imperial College London, Dept of Surgery and Cancer Hartvigsen, Jan; University of Southern Denmark, Department of Sports Science and Clinical Biomechanics; Nordic Institute of Chiropractic and Clinical Biomechanics O'Sullivan, Kieran; Aspetar Qatar Orthopaedic and Sports Medicine Hospital, Sports Spine Centre Vickery, Alistair; The University of Western Australia, General Practice Caneiro, J.P.; Curtin University, Physiotherapy and Exercise Science Schütze, Robert; Curtin University, School of Physiotherapy and Exercise Science Laird, Robert; Superspine Attwell, Stephanie; Macquarie University, Department of Health Professions Hancock, Mark; Macquarie University, Department of Health Professions
Keywords:	Low back pain, wearable devices, rehabilitation, clinical trial protocol

RESTORE – Cognitive Functional Therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain: study protocol for a randomised controlled trial

Peter Kent, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Peter O'Sullivan, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Anne Smith, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Terry Haines, PhD, School of Primary and Allied Health Care, Monash University, Melbourne, Australia

Amity Campbell, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Alison McGregor, PhD, Department of Surgery & Cancer, Imperial College, London, UK

Jan Hartvigsen, PhD, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark; Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark

Kieran O'Sullivan, PhD, Aspetar Orthopaedic and Sports Medicine Hospital, Doha; School of Allied Health, University of Limerick, Limerick, Ireland

Alistair Vickery, MBBS, University of Western Australia, Perth, Australia

J.P. Caneiro, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Rob Schutze, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Rob Laird, PhD, Superspine, Melbourne, Australia

Stephanie Attwell, PhD, Department of Health Professions, Macquarie University, Sydney, Australia

Mark Hancock, PhD, Department of Health Professions, Macquarie University, Sydney, Australia

Correspondence to: Peter Kent

Contact address: School of Physiotherapy and Exercise Science, Curtin University, Kent Street, Bentley, Western Australia, Australia, 6102

Email address: peter.kent@curtin.edu.au

Word count: 4491

ABSTRACT

Introduction: Low Back Pain (LBP) is the leading cause of disability globally and its costs exceed those of cancer and diabetes combined. Recent evidence suggests that individualised cognitive and movement rehabilitation combined with lifestyle advice (Cognitive Functional Therapy (CFT)) may produce larger and more sustained effects than traditional approaches, and movement sensor biofeedback may enhance outcomes. Therefore, this three-arm randomised controlled trial (RCT) aims to compare the clinical effectiveness and economic efficiency of individualised CFT delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

Methods and analysis: Pragmatic, three-arm, randomised, parallel group, superiority RCT comparing usual care (n=164) with CFT (n=164) and CFT-plus-movement-sensor-biofeedback (n=164). Inclusion criteria include: adults with a current episode of LBP >3 months; sought primary care ≥6 weeks ago for this episode of LBP; average LBP intensity of ≥4 (0-10 scale); at least moderate pain-related interference with work or daily activities. The CFT only and CFT-plus-movement-sensor-biofeedback participants will receive seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks. All participants will be assessed at baseline, 3, 6, 13, 26, 40 and 52 weeks. The primary outcome is pain-related physical activity limitation (Roland Morris Disability Questionnaire). Linear mixed models will be used to assess the effect of treatment on physical activity limitation across all time points, with the primary comparison being a formal test of adjusted mean differences between groups at 13 weeks. For the economic (cost-utility) analysis, the primary outcome of clinical effect will be quality-adjusted life years measured across the 12-month follow up using the EQ-5D-5L.

Ethics and dissemination: Approved by Curtin University Human Research Ethics Committee (HRE2018-0062, 6th Feb 2018). Study findings will be disseminated through publication in peer-reviewed journals and conference presentations.

Trial Registration: Australian and New Zealand Clinical Trials Register: ACTRN12618001396213

Strengths and limitations of this study:

- The first fully powered study comparing Cognitive Functional Therapy to usual care as control
- Three-arm trial to quantify the added contribution of movement sensor biofeedback to Cognitive Functional Therapy
- Evaluation of whether cognitive or movement changes mediate improvements
- Evaluation of economic efficiency in addition to clinical effectiveness
- Full participant and therapist blinding not possible

Keywords

Low back pain, wearable electronic devices, rehabilitation, clinical trial protocol

INTRODUCTION

Globally, low back pain (LBP) carries the greatest burden of disease in terms of years lived with disability[1]. Most people with an episode of LBP improve rapidly, however, many have recurrent pain and some develop chronic LBP (pain lasting >3 months) with high levels of disability[2]. This group of patients is responsible for most of the cost and burden associated with LBP[3]. The resultant societal costs of chronic LBP are enormous, exceeding that of cancer and diabetes combined[4 5], with the majority of these costs being due to loss of work participation and on-going care-seeking. Current care models are failing, with LBP-related disability increasing 45% from 1990 to 2010[6].

LBP guidelines recommend that patients seeking care for LBP are initially offered simple interventions (e.g. advice and self-management strategies) and, if they do not improve quickly, then other interventions such as anti-inflammatory medication, exercise therapy and manual therapies[7]. For those patients who fail to respond to these interventions, care is often rapidly escalated, to more invasive, expensive, and potentially harmful interventions, including opioids[8], injections[9], and surgery[10], which have limited evidence of effectiveness despite carrying substantial risks. Furthermore, these patients frequently undergo expensive imaging, which does not improve outcomes and may actually be detrimental[11]. There is an urgent need for effective 'second line' primary care interventions for those patients who do not improve with early standard management, in order to reduce chronicity and limit the number of people progressing to secondary care.

Exercise approaches are the most widely recommended interventions for patients with chronic disabling LBP[12]. A number of exercise approaches, including graded activity, Pilates

and motor control exercises, have been shown to produce small to moderate effects but with a variable duration of improvements.[13-16] One aspect this has been attributed to is a lack of individualised management of known psychological barriers to recovery and inadequate targeting of exercise to each individual's specific functional movement limitations.

Cognitive Functional Therapy (CFT) was developed as a physiotherapist-led, individualised cognitive and behavioural self-management approach to chronic disabling LBP that helps people to: 1) reconceptualise their pain from a biopsychosocial perspective, while dispelling unhelpful beliefs and identifying new cognitive and behavioral responses to pain, 2) build confidence to engage in functional activities related to their goals through functional movement training and 3) adopt a healthy lifestyle by targeting activity avoidance, poor sleep habits, stress management and dietary advice.[17] A Norwegian study of patients with chronic LBP (N=121), found CFT resulted in large sustained effect sizes (12-month standardised effect sizes from 0.7 to 0.9) compared with guideline-recommended manual therapy and exercise.[18] These findings suggest a large, high quality study is now required.

With advances in technology, movement sensors enable accurate measurement and monitoring of lumbar spine movements outside the research laboratory[19]. Wearable movement sensors enable clinicians to precisely measure movement patterns, postures (functional movements) and their relationship to pain, both in the clinical setting but more importantly, during patients' normal activities (work, rest and play) outside the clinic. In addition, movement sensors could help patients to develop an awareness of how they move and the postures they use during normal activities, where changes to these habituated functional movement behaviors are most important. This technology has the potential to increase the effectiveness of therapies aimed at correcting functional movement behaviours.

A recent pilot RCT (N=112) of patients with chronic LBP showed that individualised rehabilitation, based on addressing functional movement behaviours, combined with biofeedback from wearing wireless movement sensors, resulted in large and sustained clinical improvements compared with guideline-recommended treatment (12-month effect sizes from 0.5 to 1.0).[20]

Therefore, this three-arm RCT aims to compare the clinical effectiveness and economic efficiency of individualised CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

METHODS AND ANALYSIS

The RESTORE study is a pragmatic, three-arm, parallel group, superiority RCT comparing usual care with CFT only and CFT-plus-movement-sensor-biofeedback in patients with chronic LBP (Figure 1). The trial will be conducted in Perth and Sydney, Australia. Curtin University Human Research Ethics Committee approved the study (HRE2018-0062, 6 February 2018) and the trial is registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12618001396213). The protocol follows the SPIRIT recommendations[21].

Participants

We will recruit 492 adult participants who meet these inclusion criteria: a current episode of LBP lasting more than 3 months; presenting to a primary care clinician at least 6 weeks ago for this episode of LBP; scoring an average LBP intensity of 4 or more on a 0-10 Numerical Rating Scale[22]; and having at least moderate pain-related interference with normal work or daily activities (measured by item 8 of the SF-36)[23]. Patients will be excluded if they have any diagnosed medical conditions that prevent them from being physically active; have a

serious spinal pathology (e.g. fracture, infection, cancer); are pregnant or have given birth within the previous 3 months; have inadequate English to comprehend the study's questionnaires and instructions; have a skin allergy to hypoallergenic band-aid or tape adhesives; or are scheduled for major surgery in the next 3 months. In addition to those inclusion criteria, participants will be informed of the locations of the physiotherapy clinics for the study intervention groups and will only be included in the trial if they are willing to travel for treatment to at least one site delivering either of the possible interventions.

Patient and public involvement

Patients and the Public were not directly involved in the design, recruitment to or conduct of this study. They will be involved in our plans to disseminate the study results to participants and relevant community groups, by assisting in the choice of what information/results to share, and in what format.

Recruitment

Trial participants will be recruited via clinicians (e.g. GPs, physiotherapists, pain clinics, surgeons), or directly from the community (e.g. via print media and social media). Clinicians will conduct a preliminary screening of patients with LBP and inform potential trial participants about the study. Those patients who request further information about the study will be provided with a flyer, which directs them to the study website (https://www.restorebackpain.com/) where greater study details, including the participant information sheet and consent form, are provided. Potential participants can opt to have the research team contact them or can simply take the study flyer and contact the research team directly.

Participants will also be recruited directly from the community, without a health practitioner referral. Information about the trial will be disseminated via social media (including Facebook, LinkedIn, Twitter etc.) and print media (including flyers, newsletters, etc.) which will direct to the website and the research team.

All potential participants will be screened for eligibility over the phone by a researcher prior to inclusion. The researcher will also note in the trial database any reasons for excluding a referred patient but not any identifying details of that person. Recruitment into RESTORE commenced on 23 October 2018.

Consent process

Consent will be sought from potential participants who meet the inclusion criteria. A researcher will discuss the trial protocol and offer participants the opportunity to provide consent electronically or by mail (Appendix 1). Electronic consent for the trial will be via a weblink to an electronic version of the consent form. The consent form also asks patients to indicate whether they are comfortable or not with videos being taken of some treatment sessions. Videos are used to monitor fidelity of the physiotherapist in delivering the individualised rehabilitation as per the study protocol. Participants can withdraw for any reason at any time.

All recruited patients will be asked to provide consent for access to their Medicare and Pharmaceutical Benefits Scheme records for the 12-month time period that they are involved in the study. These data will be only used for the analysis of economic efficiency. A paper version of the Federal Department of Human Services-supplied consent form will be sent to

participants for signing and returning via a postage-paid envelope. Declining this consent will not affect eligibility to participate in the clinical effectiveness component of the trial.

Baseline assessment

Following informed consent, participants will self-complete the baseline assessment, including patient demographics and outcome measures, via the online database. A researcher will be available by phone if they require assistance. A detailed description of the baseline variables is provided in Table 1.

Randomisation

After completing the baseline assessment, dynamic (adaptive) random allocation will be used to randomise participants to treatment groups. Randomisation using a 1:1:1 allocation ratio will be conducted by a research assistant by phoning the NHMRC Clinical Trials Centre (24-hour phone service), thereby ensuring concealment of treatment allocation. The NHMRC Clinical Trials Centre will be blinded to baseline assessment. After randomisation and only for those randomised to the CFT-only and CFT-plus-movement-sensor-biofeedback groups, a research assistant will make an appointment for them with a study clinician at an accessible location in their city.

Study treatment

Group 1: Usual care

This treatment will be the usual care pathway the participant's health providers recommend and/or the participant chooses. Treatment in this group will not be impacted in any way by participation in the study. Participants in this group only will be paid a token reimbursement for their time completing follow-up questionnaires (AU$30 for the 3-month questionnaire,

$30 for the 12-month questionnaire and an additional $50 if they complete all the six follow-up questionnaires (3 and 6 week, 3, 6, 9 and 12 month).

Commonalities across the two CFT treatment groups (Groups 2 and 3)

Both CFT treatment groups will have the same treatment frequency of seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks (initial consultation 60 minutes, follow ups 30-40 minutes), in physiotherapy clinics. In both groups, clinicians will use a structured approach to address the relevant cognitive, emotional and behavioural (functional and lifestyle) factors deemed relevant to the individual's presentation[17].

Based on prior screening (Orebro Musculoskeletal Pain Questionnaire and the Patient-Specific Functional Scale) combined with a comprehensive interview and functional examination, the clinician will identify the multidimensional contributors to pain, distress and disability. This will enable the physiotherapist to design a management plan that is tailored to the person's unique clinical presentation and context.

There are three broad components to the intervention:

Making sense of pain: a reflective process that combines the person's own narrative (interview) and experience (during guided behavioural experiments) to develop a personally-relevant, multidimensional understanding of pain for the patient. In this process, unhelpful beliefs and responses to pain are disconfirmed, and new helpful cognitive and behavioural responses (functional and lifestyle) to pain are identified that are linked to their personally relevant goals[17].

Exposure with 'control': a process of behavioural change through experiential learning

following a 'graded exposure' model, designed to challenge expectations of pain and damage consequences via guided behavioural experiments. Specifically, sympathetic nervous system responses (rapid upper chest breathing and body tension) and safety-seeking behaviours (protective muscle guarding, breath-holding, movement avoidance and propping of the hand) that manifest during exposure to painful, feared or avoided functional tasks are explicitly targeted and controlled. This provides patients with strategies to relax, control respiration, normalise postural and movement behaviours that they nominate as painful, feared or avoided. The new strategies are immediately integrated into goal orientated daily activities to build self-efficacy and body conditioning.

Lifestyle change: behavioural modification addressing unhelpful lifestyle factors aimed at increasing physical activity levels based on preference, sleep habits, regulation of stress (via relaxation techniques) and/or dietary advice, where relevant.

CFT is underpinned by a strong therapeutic alliance and motivational interviewing style (open, non-judgmental, reflective)[17] providing validation and facilitating disclosure[24 25]. An individualised progressive self-management program will be provided, monitored and progressed that includes cognitive restructuring, progressive functional exercises and lifestyle changes, tailored to the individual's goals.

All participants in the CFT-only and CFT-plus-movement-sensor-biofeedback groups will wear the movement sensors for the same duration and frequency, but for the CFT-only group, the movement sensors will be a placebo, meaning that the sensors will collect data but neither the patient nor the clinician will have access to it (only the researchers have access). The ViMove2 device (DorsaVi P/L, Melbourne, Australia) consists of miniaturised sensors

attached to the lumbar spine with hypoallergenic tape, and communicate wirelessly with a tablet or mobile phone (Figure 2). At all treatment sessions, patients in both CFT groups will perform forward bending in standing and two other clinically-relevant functional movements selected by the physiotherapist based in the patient specific functional scale. All three movements will be repeated three times and data recorded via the movement sensors.

Differences across the two CFT treatment groups

Group 2: Cognitive Functional Therapy only (CFT-only)

Clinicians and patients in this group will be blinded to all movement sensor output by a software block that only allows the sensors to be configured/started and for the data to be automatically uploaded to a secure cloud-based server. Participants will be told the device is being used to collect outcome data.

Group 3: CFT-plus-movement-sensor assessment and biofeedback (CFT-plus-movement-sensor-biofeedback)

Clinicians in this group will treat patients with the same CFT approach as in the CFT-only group except that in addition, these clinicians will have access to data measured by the movement sensors and be able to use these data for assessment, movement retraining and providing biofeedback. The identification of clinically relevant functional movement behaviors in this particular treatment group will also be informed by data from the movement sensors that are graphically analysed and displayed by the ViMove2 software (Figure 3).

This additional information could assist in guiding individualised movement retraining incorporating the following strategies. Firstly, 'live assessment' can assist in identifying unusual kinematic parameters or movement patterns.[26] Secondly, 'live training' in the clinic,

allows visual interaction by observing real-time kinematic and EMG on-screen data to facilitate changing functional movement behaviours. Thirdly, using the ViMove2 software, clinicians can program movement sensor biofeedback alerts (audio 'beeps' and messages via a trial-supplied iPhone) that will reinforce key principles from the treatment session while the participant goes about their normal daily activities for the rest of the day. The device will prompt the patient when they 'break a movement rule' that has been programmed for them by the clinician. Individualised movement 'prompts' may be time-based, such as reducing long periods of sitting without getting up and moving, or may be kinematically-based, such as reducing sitting in an excessively upright position.

There is no provision for trial-funded ancillary or post-trial care.

Clinician recruitment and training

Depending on recruitment and training success, approximately 16 physiotherapists (8 in each city) will deliver the interventions at private physiotherapy clinics. Each physiotherapist will deliver only one CFT treatment arm, to prevent learning (contamination) from experience using the movement sensor output being applied to the CFT-only patients. Physiotherapists will be randomised into either the CFT-only group or CFT-plus-movement-sensor-biofeedback group. Up to four additional physiotherapists will be recruited and trained in each city to act as reserves if required. For physiotherapists to be considered for inclusion in the training program, they will need to have: at least 2 years clinical experience post-graduation; experience treating people with chronic LBP; an interest in applying biopsychosocial management principles via CFT; a willingness to use movement sensors clinically; less than 4 days of prior exposure to CFT training; and a willingness to be

observed and videoed for mentoring and feedback purposes while treating a *non-trial* patient with disabling LBP.

The clinician training for both the CFT-only group and CFT-plus-movement-sensor-biofeedback group will consist of three components: (i) clinical workshops including live patient demonstrations and mentoring of the physiotherapists while treating patients, (ii) online resources (e.g. e-book and training videos) and (iii) Facebook private support group pages.

CFT training

Six clinical workshops will be conducted (a two-day workshop every month for 6 months) in each city where both CFT-only and CFT-plus-movement-sensor-biofeedback groups will train together. A final single day workshop will be held for each group separately when clinicians will need to demonstrate a pre-defined level of competency, as evaluated by the CFT and movement sensor clinical trainers using a structured competency check-list, before being eligible to deliver the relevant intervention in the trial. The training workshops will include an initial introductory workshop about CFT with patient involvement, a workshop to build skills regarding communication and behavioural experiments, and four workshops involving observation of each physiotherapist examining and treating people with disabling LBP using CFT. The later four sessions will be observed by the clinical trainers, who will provide personalised feedback using a competency checklist developed for the training. The CFT training will be conducted by physiotherapists (POS and JPC) who developed the CFT approach and have extensive experience using and teaching CFT. Clinical competency will be assessed in a final one-day workshop, or by ongoing videos of patients if required.

Movement sensor training

Because the ViMove2 movement sensors are worn by participants in both CFT groups, all participating clinicians will attend a 2-hour technical workshop on setting up and using the ViMove2 devices. This workshop will focus on sensor placement, how to test they are working and how to troubleshoot technical issues. The training will occur after the 6th training workshop and at least 2 weeks before the final single-day workshop. The clinicians in the CFT-plus-movement-sensor-biofeedback group will attend a second 4-hour workshop on accessing and interpreting the movement data (kinematic and EMG) and programming biofeedback. These movement sensor workshops will be conducted by a physiotherapist (RL) with extensive experience using these movement sensors clinically and teaching clinicians in their use. Personalised mentoring by RL will be available over the phone to each physiotherapist for up to five post-hoc reviews of treatment sessions of trial participants.

Ongoing support for both clinician groups

During the trial, private Facebook pages (one on CFT, one on movement sensors for the CFT-only group and one on movement sensors for the CFT-plus-movement-sensor-biofeedback group) and 3-monthly virtual or face-to-face meetings with a clinical trainer will be provided for both clinician groups separately to provide a forum for the discussion of challenges faced when implementing the intervention or with technical issues related to the sensors. The trainers will contribute to the Facebook discussion and 3-monthly meetings.

Treatment fidelity checking

Every seventh participant of each clinician will be selected, and their treatment monitored by the appropriate clinician trainer to ensure ongoing treatment fidelity. If the seventh participant does not consent to this occurring, each subsequent participant of that clinician

will be asked until one consents. This process is recommended in the Spillane (2007)[27] framework for implementation fidelity in trials. This will take the form of video recordings of three consultations (a consultation early in the treatment process, one in the middle and one close to the end of the treatment period) that will be reviewed by a randomly selected clinician trainer (POS, JPC or KOS) with brief feedback provided if required.

Data collection and outcome measures

Data collection will occur at baseline, and at 3, 6, 13, 26, 40 and 52 weeks. Where ever possible, all data will be completed on-line directly into the trial database. Alternatively, patients can complete follow ups over the telephone with a researcher. If participants do not complete follow-ups within 2 day of the scheduled date, they will receive an email reminder and then 2 days later will contacted by one of the study team. Data collected via the ViMove sensors at each clinical visit will be directly uploaded to a database. A detailed description of the data collected at each time point is presented in Table 1.

Primary outcomes

The primary clinical outcome will be pain-related physical activity limitation measured using the Roland Morris Disability Questionnaire[28 29] (RMDQ). For the economic efficiency (cost-utility) analysis, the primary outcome of clinical effect will be quality-adjusted life years calculated using the area under the curve approach based on responses to the EQ-5D-5L questionnaire[30] across each of the assessment time points.

Secondary outcomes

The secondary outcomes include:

- Pain intensity (three numeric rating scales)[31]

- Patient-specific activity limitation (Patient-Specific Functional Scale)[32]
- Pain catastrophisation (Pain Catastrophizing Scale)[33]
- Pain self-efficacy (Pain Self-efficacy Questionnaire)[34]
- Fear of movement (physical activity subscale of the Fear Avoidance Beliefs Questionnaire)[35]
- Patient-perceived global improvement (1 question)[36]
- Patient satisfaction with care and treatment (1 question)[37]
- Adverse events (defined as any morbidity or events causing unwarranted distress to a participant that were potentially related to any trial-related intervention). Clinicians and follow-up questionnaires will inquire about any adverse events.
- Lumbosacral movement will be measured in both CFT treatment groups using ViMove2 wearable wireless sensors and used in the mediation analysis.
- Direct health costs attributable to consumption of health care resources (measured using extracts from Medicare and Pharmaceutical Benefits databases and direct patient reports) and productivity costs (measured using the iMTA Productivity Cost Questionnaire[38]).

Sample size calculation

The sample size was calculated for the primary outcome using the program STATA. A total of 492 patients (164 per group) will be recruited to detect a difference of 2 points (0-24 scale) on the RMDQ between the CFT-only group and CFT-plus-movement-sensor-biofeedback group, $p<0.05$, 80% power, a common standard deviation of 6 points and a worst-case scenario of 20% drop-out rate. Based on our pilot study results[20 39], we hypothesise that the CFT-plus-movement-sensor-biofeedback group would have an average score of 7.5 points on the RMDQ and the Usual care group would have a score of 11.5 points. Pragmatically and arbitrarily, we assume the CFT-only group will have a mean outcome that is half-way (9.5)

between the other two groups and so we will power the trial to detect this as the smallest likely between-group difference (11.5-9.5=2.0).

Blinding

Patients will not be informed of any anticipated results of the trial and will be told that the trial is comparing usual care to two evidence-based interventions. All outcome measures will be either self-reported by patients via web-based questionnaires or collected via the movement sensors or MBS/PBS registers. Unblinded clinicians will deliver only type of one treatment and play no role in collecting data, other than performing a standardised movement protocol with the resultant movement data being automatically uploaded by the sensors to a server without clinician input. Statisticians will be blind to groups.

Statistical analysis

Almost all participant-reported data will be entered directly into an electronic database, where range values are automatically checked. In addition, all data will be checked for range values and outliers prior to analysis.

Treatment efficacy analysis

Repeated-measure linear mixed models will be used to assess the effect of treatment on pain-related physical activity limitation across all time points (3, 6, 13, 26, 40 and 52 weeks), with the primary comparison being a formal test of adjusted mean differences between groups at 13 weeks using intention-to-treat principles. Appropriate sensitivity analyses will be performed on multiple imputed datasets. Estimates of treatment effect will be adjusted for baseline scores of symptom duration, pain intensity, activity limitation (RMDQ score), treatment expectations and significant clinician cluster effects.

The secondary outcome measures will be evaluated using the equivalent repeated-measure linear mixed models.

Analysis of economic efficiency

Direct healthcare and indirect (productivity) costs incurred by participants will be measured over the 12-month follow-up period. Direct health costs will be collected using Medicare Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS) database extractions, and patient questionnaires to capture other health care costs (e.g. hospitalisations). Indirect health costs (e.g. travel to appointments) and productivity costs (including absenteeism and presenteeism) will also be captured in the 3-monthly patient questionnaires. Productivity costs will be measured using the 'iMTA Productivity Cost Questionnaire'. Productivity costs measured at specific time points will be extrapolated to the full one-year period using an area under the curve approach. All costs will be calculated using a 2019-2020 financial base year. Hospital costs will be valued using the National Weighted Activity Unit calculators for the 2019-2020 year.

An incremental cost-utility analysis will calculate the difference in costs between intervention and control groups divided by the difference in quality-adjusted life years. Incremental cost-utility analyses will be undertaken from societal (primary analysis) and health service (secondary analysis) perspectives. There will also be analyses undertaken for valuation of productivity costs using human capital (primary analysis) and friction (secondary analysis) methods. Bootstrap resampling (2000 replications of original sample size) will be used to generate a 95% confidence ellipse surrounding the incremental cost-utility estimate. Cost-effectiveness acceptability curve analyses will be undertaken if the intervention is not found to dominate the control condition.

Moderation analysis

To investigate if treatment effect is moderated by cognitive flexibility, baseline activity limitation, baseline pain, catastrophisation or self-efficacy (all groups), the interaction term between the potential moderator and the treatment group variable will be assessed in the repeated-measure linear mixed models for pain-related activity limitation and pain intensity described above. Only in the CFT groups, similar moderation analysis will also occur using the STaRT MSK Tool[40 41] (measured at baseline), therapeutic alliance[42] (measured at 3 weeks) and participant-rated adherence to the treatment program measured at weeks 3, 6 and 12 with a study-specific single question ('How would you rate your adherence to the treatment program your physiotherapist has recommended?' 0-10 no adherence to complete adherence).

Mediation analysis

To investigate whether improvement in patients' activity limitation was mediated by correction of habituated functional movement behaviors, or changing patient's pain-related cognitions and emotions, a multilevel structural equation model framework will be utilised. Investigation of the mediation roles of cognitions and emotions will occur using data from all patients; whereas, investigation of the mediation roles of change in movement will occur using data from only patients in the CFT groups. Results will be expressed as standardised estimates of mediated treatment effect with bootstrapped 95% confidence intervals.

Monitoring:

Because this is not a drug trial and the funder has no access to the data, a data monitoring committee will not be formed and there is no planned trial audit. This does not preclude the

administering institution choosing to conduct an audit. There will be no interim analysis and, due to the very low risk of harm, there are no stopping guidelines.

Ethics and dissemination:

This study will be conducted in accordance with the Therapeutic Goods Administration's Note for Guidance on Good Clinical Practice, the NHMRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

Authorship will be based on the Vancouver Convention[43] and no professional writers will be involved.

Any protocol amendments will be detailed in the trial registration (ACTRN12618001396213).

Metadata and appropriate copies of publications will be deposited in the Curtin University eSpace, which is an open access digital repository.

Results will be disseminated via publications in peer-reviewed scientific journals, popular press articles, social media and presentations to scientific and general public audiences.

De-identified data and statistical code will be made available on request soon after each report of the data has been published. Different aspects of the data will be published separately, which will determine when those data are publicly available. A data-sharing

agreement will require a commitment to using the data only for specified research purposes, to securing the data appropriately and to destroying the data after a nominated period.

Acknowledgments

The investigators acknowledge the National Health & Medical Research Council (grant number 1145271).

References

1. Hoy D, March L, Brooks P, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis* 2014;73(6):968-74. doi: 10.1136/annrheumdis-2013-204428
2. Kongsted A, Kent P, Axen I, et al. What have we learned from ten years of trajectory research in low back pain? *BMC Musculoskelet Disord* 2016(17:220) doi: DOI 10.1186/s12891-016-1071-2
3. Shelerud RA. Epidemiology of occupational low back pain. *Clin Occup Environ Med* 2006;5(3):501-28.
4. Institute of Medicine Committee on Advancing Pain Research C, Education. The National Academies Collection: Reports funded by National Institutes of Health. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US) National Academy of Sciences. 2011.
5. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Arch Phys Med Rehabil* 2014;95(5):986-95.e1. doi: 10.1016/j.apmr.2013.10.032
6. Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380(9859):2224-60. doi: 10.1016/s0140-6736(12)61766-8
7. Wong JJ, Cote P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. *Eur J Pain* 2017;21(2):201-16. doi: 10.1002/ejp.931
8. Deyo RA, Von Korff M, Duhrkoop D. Opioids for low back pain. *BMJ* 2015;350:g6380. doi: 10.1136/bmj.g6380
9. Staal JB, de Bie RA, de Vet HC, et al. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. *Spine* 2009;34(1):49-59. doi: 10.1097/BRS.0b013e3181909558
10. Fritzell P, Hagg O, Nordwall A. Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish Lumbar Spine Study Group. *Eur Spine J* 2003;12(2):178-89. doi: 10.1007/s00586-002-0493-8
11. Webster BS, Choi Y, Bauer AZ, et al. The cascade of medical services and associated longitudinal costs due to nonadherent magnetic resonance imaging for low back pain. *Spine* 2014;39(17):1433-40. doi: 10.1097/brs.0000000000000408
12. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Int Med* 2017 doi: 10.7326/m16-2367
13. Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018 9;391(10137):2368-2383. doi: 10.1016/S0140-6736(18)30489-6.
14. Yamato TP, Maher CG, Saragiotto BT, et al. Pilates for low back pain. *Cochrane Database Syst Rev* 2015(7):CD010265. doi: 10.1002/14651858.CD010265.pub2

15. Saragiotto BT, Maher CG, Yamato TP, et al. Motor control exercise for chronic non-specific low-back pain. *Cochrane Database Syst Rev* 2016(1):Cd012004. doi: 10.1002/14651858.Cd012004
16. van der Giessen RN, Speksnijder CM, Helders PJ. The effectiveness of graded activity in patients with non-specific low-back pain: a systematic review. *Disabil Rehabil* 2012;34(13):1070-6. doi: 10.3109/09638288.2011.631682
17. O'Sullivan PB, Caneiro J, O'Keeffe M, et al. Cognitive functional therapy: an integrated behavioral approach for the targeted management of disabling low back pain. *Phys Ther* 2018;98(5):408-23.
18. Vibe Fersum K, O'Sullivan P, Skouen JS, et al. Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: A randomized controlled trial. *Eur J Pain* 2013;17(6):916-28. doi: 10.1002/j.1532-2149.2012.00252.x.
19. Adams MA, Dolan P. Spine biomechanics. *J Biomech* 2005;38(10):1972-83. doi: 10.1016/j.jbiomech.2005.03.028
20. Kent P, Laird R, Haines T. The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial. *BMC Musculoskelet Disord* 2015;16(1):131.
21. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Int Med* 2013;158(3):200-7. doi: 10.7326/0003-4819-158-3-201302050-00583
22. Manniche C, Asmussen K, Lauritsen B, et al. Low Back Pain Rating scale: validation of a tool for assessment of low back pain. *Pain* 1994;57(3):317-26.
23. Medical Outcomes Trust. SF-36 health survey scoring manual for English language applications: Australia/New Zealand, Canada, United Kingdom. Boston: Medical Outcomes Trust, 1994.
24. Linton SJ. Intricacies of good communication in the context of pain: does validation reinforce disclosure? *Pain* 2015;156(2):199-200. doi: 10.1097/01.j.pain.0000460297.25831.67
25. Edmond SN, Keefe FJ. Validating pain communication: current state of the science. *Pain* 2015;156(2):215-9. doi: 10.1097/01.j.pain.0000460301.18207.c2
26. Laird RA, Keating JL, Kent P. Subgroups of lumbo-pelvic flexion kinematics are present in people with and without persistent low back pain. *BMC Musculoskelet Disord* 2018;19(1):309. doi: 10.1186/s12891-018-2233-1
27. Spillane V, Byrne MC, Byrne M, et al. Monitoring treatment fidelity in a randomized controlled trial of a complex intervention. *J Adv Nurs* 2007;60(3):343-52. doi: 10.1111/j.1365-2648.2007.04386.x
28. Lauridsen HH, Hartvigsen J, Manniche C, et al. Responsiveness and minimal clinically important difference for pain and disability instruments in low back pain patients. *BMC Musculoskelet Disord* 2006;7:82. doi: 10.1186/1471-2474-7-82
29. Patrick D, Deyo R, Atlas S, et al. Assessing health related quality of life in patients with sciatica. *Spine* 1995;20(17):1899-908.
30. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
31. Ross R, LaStayo P, editors. *Clinical Assessment of Pain*. Philadelphia: WB Saunders Co, 1997.

32. Hall AM, Maher CG, Latimer J, et al. The patient-specific functional scale is more responsive than the Roland Morris disability questionnaire when activity limitation is low. *Eur Spine J* 2011;20(1):79-86. doi: 10.1007/s00586-010-1521-8
33. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. *Psychol Assess* 1995;7(4):524.
34. Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *EurJ Pain* 2007;11(2):153-63.
35. Waddell G, Newton M, Henderson I, et al. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52(2):157-68.
36. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009;17(3):163-70.
37. Foster NE, Thomas E, Hill JC, et al. The relationship between patient and practitioner expectations and preferences and clinical outcomes in a trial of exercise and acupuncture for knee osteoarthritis. *Euro J Pain* 2010;14(4):402-9. doi: 10.1016/j.ejpain.2009.06.010
38. Bouwmans C, Krol M, Severens H, et al. The iMTA Productivity Cost Questionnaire: A Standardized Instrument for Measuring and Valuing Health-Related Productivity Losses. *Value Health* 2015;18(6):753-8. doi: 10.1016/j.jval.2015.05.009
39. Vibe Fersum K, O'Sullivan P, Skouen J, et al. Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: A randomized controlled trial. *Eur J Pain* 2013;17(6):916-28.
40. Campbell P, Hill JC, Protheroe J, et al. Keele Aches and Pains Study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. *J Pain Res* 2016;9:807-18. doi: 10.2147/jpr.S116614
41. Dunn KM, Campbell P, Afolabi EK, et al. 176. Refinement and validation of the Keele STarT MSK Tool for musculoskeletal pain in primary care. *Rheumatology* 2017;56(suppl_2)
42. Hall AM, Ferreira ML, Clemson L, et al. Assessment of the therapeutic alliance in physical rehabilitation: a RASCH analysis. *Disabil Rehab* 2012;34(3):257-66.
43. International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors [Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html accessed 21 February 2019.
44. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8(2):141-4.
45. Stratford P, Gill C, Westaway M, et al. Assessing disability and change on individual patients: a report of a patient specific measure. *Physiother Can* 1995;47(4):258-63.
46. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20(10):1727-36.
47. Rofail D, Myers L, Froggatt D. Treatment Satisfaction and Dissatisfaction in Chronic Low Back Pain: a Systematic Review. *J Psychol Psychother* 2016;6:260.
48. Martin MM, Rubin RB. A new measure of cognitive flexibility. *Psychol Rep* 1995;76(2):623-26.
49. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009;17(3):163-70.
50. Larsen DL, Attkisson CC, Hargreaves WA, et al. Assessment of client/patient satisfaction: development of a general scale. *Eval Prog Plann* 1979;2(3):197-207.

51. Bouwmans C, Krol M, Severens H, et al. The iMTA productivity cost questionnaire: a standardized instrument for measuring and valuing health-related productivity losses. *Value Health* 2015;18(6):753-58.
52. World Health Organization. International ethical guidelines for health-related research involving humans: Geneva: Council for International Organizations of Medical Sciences 2016.

Authors' contributions:

PK and MH wrote the initial draft manuscript. All authors (PK, POS, AS, TH, AC, AM, JH, KOS, AV, JPC, RS, RL, SA and MH), contributed to and revised subsequent drafts and approved the final version.

Funding statement:

This work is supported by National Health and Research Council (www.nhmrc.gov.au) grant number APP1145271, however the Council has no role in study design, data collection, management, analysis, and interpretation of data, writing of reports and the decision to submit any report for publication. The trial team will have unrestricted access to the final trial dataset.

Competing interests statement:

JPC, KOS and POS deliver continuing education workshops on Cognitive Functional Therapy, for which they receive honoraria. The authors declare no other competing interests.

Figure legends:

Figure 1: Flow chart

Figure 2: Placement of the ViMove2 movement sensors

Figure 3: Example movement data (flexion) graphically analysed and displayed by the ViMove2 software

Protocol version:

Version 1, 12 April 2019

Table 1: Trial data collected and their purpose

Construct	**Measure**	**Time points (weeks)**	**Purpose**
Age	Date of birth	0	Describe population
Sex	Male/Female	0	Describe population
Duration of episode	Weeks	0	Describe population
Duration since care-seeking	Weeks	0	Describe population
Previous lifetime episodes	Number	0	Describe population
Height	Centimeters	0	Describe population
Weight	Kilograms	0	Describe population
Education	Categorical	0	Describe population
Current role	Categorical	0	Describe population
Employed	Yes/No	0	Describe population and analysis of economic efficiency
Occupation	Open text	0	Describe population and analysis of economic efficiency
Hours working	Hours	0	Describe population and analysis of economic efficiency
Days working	Days	0	Describe population and analysis of economic efficiency
Sick leave last 3/12	Yes/No	0, 12, 26, 40 and 52	Describe population and analysis of economic efficiency
Days of sick leave 3/12	Days	0, 12, 26, 40 and 52	Describe population and analysis of economic efficiency
Pain-related physical activity limitation	Roland Morris Disability Questionnaire[44]	0, 3, 6, 12, 26, 40 and 52	Describe population, primary outcome, analysis of economic efficiency

Functional limitation	Patient-Specific Functional Scale[45]	0, 3, 6, 12, 26, 40 and 52	Secondary outcome
Pain intensity	Numeric Pain Rating Scales[31]	0, 3, 6, 12, 26, 40 and 52	Describe population, secondary outcome
Fear avoidance beliefs	Fear Avoidance Beliefs Questionnaire (physical activity sub-scale)[35]	0, 12, 26, 40 and 52	Describe population, secondary outcome, mediator
Analgaesic use	Participant self-report text box	0	Describe population, secondary outcome (when matched to 12-month Pharmaceutical Benefits Scheme data)
Catastrophising	Pain Catastrophizing Scale[33]	0, 3, 6, 12, 26, 40 and 52	Describe population, secondary outcome, mediator and moderator
Pain self-efficacy	Pain Self-efficacy Questionnaire[34]	0, 3, 6, 13, 26, 40 and 52	Describe population, secondary outcome, mediator and moderator
Quality-adjusted life years	EuroQOL EQ-5D-5L[46]	0, 12, 26, 40 and 52	Analysis of economic efficiency outcome
Treatment expectations	A tailored question, based on Rofail, Myers and Froggatt 2016[47]	0 (post-randomisation)	Clinical effectiveness baseline covariate
Confidence in intervention	A tailored question, based on Rofail, Myers and Froggatt 2016[47]	3 (CFT groups only)	Mediator
Cognitive flexibility	Cognitive Flexibility Inventory[48]	0	Moderator
Therapeutic alliance	Working Alliance/ Theory of Change Inventory[42]	3 (CFT groups only)	Moderator
Risk stratification	STarT MSK Tool[41]	0	Moderator
Patient-perceived global improvement	Tailored question, based on Kamper et. al. 2009 recommendations[49]	12, 26, 40 and 52	Secondary outcome
Satisfaction with care and treatment	Tailored question, based on Client Satisfaction Questionnaire[50]	12	Secondary outcome

Productivity costs	iMTA Productivity Cost Questionnaire[51] (iPCQ)	12, 26, 40 and 52	Analysis of economic efficiency
Direct health costs attributable to consumption of health care resources	Extracts from Medicare and Pharmaceutical Benefits Scheme databases and direct patient report	12, 26, 40 and 52	Analysis of economic efficiency
Functional movement	Wearable wireless sensors (DorsaVi P/L)	Every consultation (CFT groups only)	Mediator
Adverse events	Tailored question, based on recommendations of the CIOMS Working Group VI[52]	3, 6, 12, 26, 40, 52 and every consultation	Monitoring adverse events

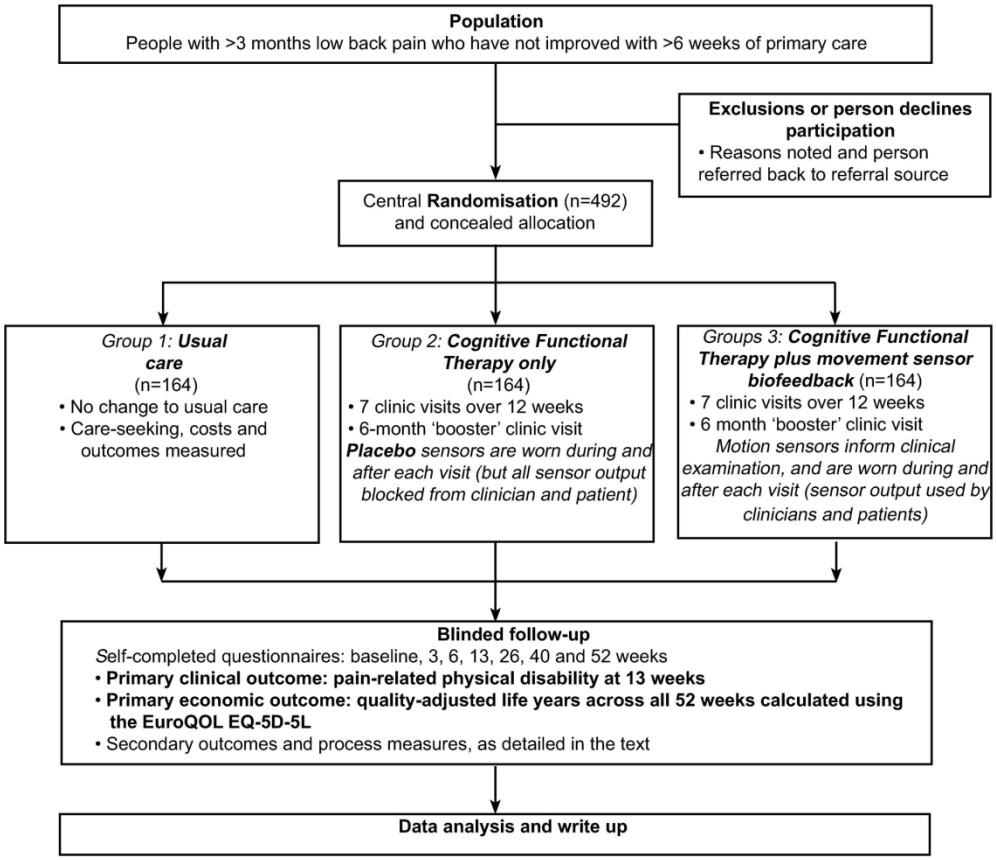
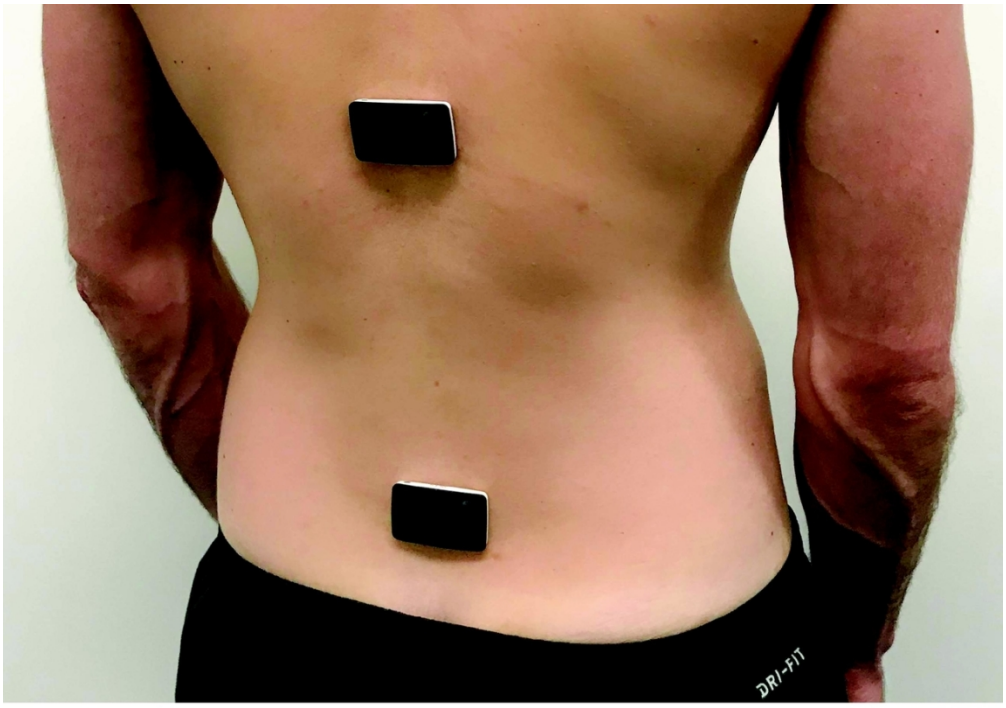


Figure 1: Flow chart

173x154mm (300 x 300 DPI)



Hypoallergenic over-wraps are applied when used during normal daily activities. When EMG sensors are included, they are placed paraspinally at the L3 level.

Figure 2: Placement of the ViMove2 movement sensors

109x91mm (300 x 300 DPI)

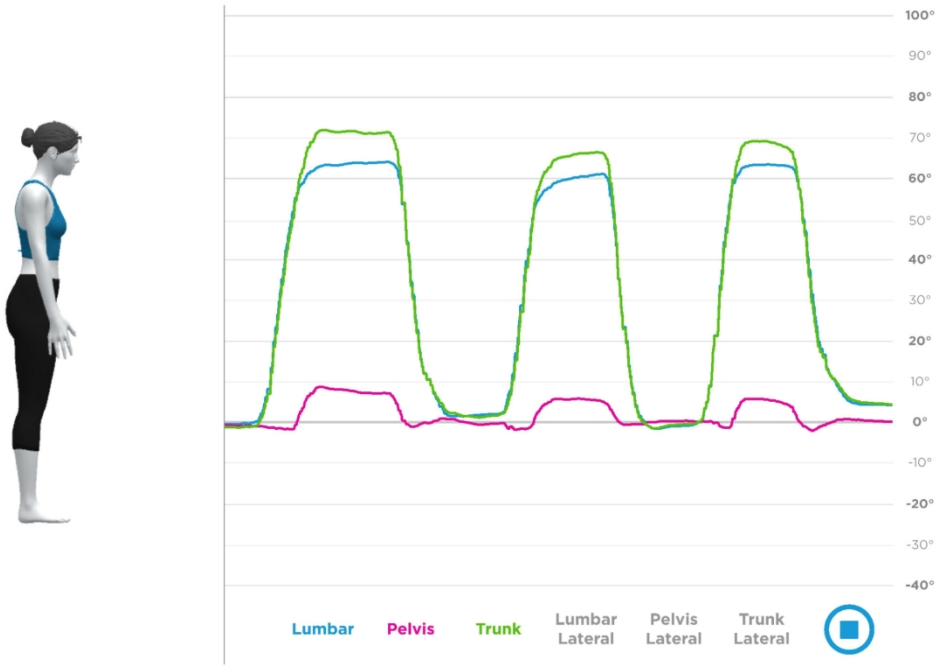


Figure 3: Example movement data (flexion) graphically analysed and displayed by the ViMove2 software

175x119mm (300 x 300 DPI)

Appendix 1: Consent form (paper version)

RESTORE clinical trial

CONSENT FORM

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2018-0062). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au

HREC Project Number	
Project Title	'RESTORE - Individualised movement rehabilitation for chronic, disabling low back pain'
Principal Investigator	Associate Professor Peter Kent, PhD
Version Number	Version 7
Version Date	22 November 2018

- ☐ I have read the Participant Information Sheet and I understand its contents
- ☐ I believe I understand the purpose, extent and possible risks of my involvement in this project.
- ☐ I voluntarily consent to take part in this research project and I know I can refuse or withdraw at any time.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- ☐ I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – updated May 2015.
- ☐ I consent to the storage and use of my information in future ethically-approved research projects.
- ☐ If I have been advised not to exercise, I consent to having a Research Assistant contact my GP to clarify whether participating in this project will be appropriate for me.
- ☐ If I am receiving third-party compensation due to my low back pain, I consent to having a Research Assistant contact my case manager to clarify whether participating in this project will be appropriate for me.
- ☐ I understand that I will receive a copy of this Consent Form and the Participant Information Sheet.
- ☐ I understand that if I am in one of the individualised rehabilitation groups, there is a random 1 in 7 chance that three of my treatment sessions might be selected to be potentially videoed. The purpose is to ensure that my physiotherapist is delivering the individualised rehabilitation in the ideal way. If I am selected, I do / do not give permission (please tick the preferred answer) for up to three of my treatment sessions being videoed for that purpose, understanding that I may participate in the trial regardless of the way I answer this:
  - Yes, I give permission ☐ No, I do not give permission ☐
- ☐ I understand that I have the option of consenting to the use of my Medicare / Pharmaceutical Benefits data for the 12 months period of my involvement in the trial and that if I agree to this option, I will be mailed a consent form for my signature. I tick my preferred answer below, understanding that I may participate in the trial regardless of the way I answer this:
  - Yes, I will give permission ☐ No, I will not give permission ☐
  - If yes, please provide a postal address to which we can post the consent form:

Participant Name	
Participant Signature	
Date	

RESTORE clinical trial

Declaration by researcher: I have supplied a Participant Information Sheet and Consent Form to the participant who has signed above, and believe they understand the purpose, extent and possible risks of their involvement in this project.

Researcher Name	
Researcher Signature	
Date	

Reporting checklist for protocol of a clinical trial.

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	P4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	Throughout manuscript
Protocol version	#3	Date and version identifier	P28
Funding	#4	Sources and types of financial, material, and other support	P28
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	P28
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	P28
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	P21

Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	P6
Objectives	#7	Specific objectives or hypotheses	P6, P7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	P7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P8, P11
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P7, P8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P10-14
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	P9
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	P17
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	P17,

		pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Table 1
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, Table 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P18
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	P8, P9
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P10
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P10
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P19

Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Allocation is not blinded to trial staff
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P17, Table 1
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P17
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P19
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P19
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P21
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P19
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	P21

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	P22
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P31
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	P21
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P7
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	P22
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Appendix 1
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P22
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	P28

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P28
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	P14. No provision for compensation, as this type of physiotherapy is a very low risk intervention.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P22
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	P22
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P22
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a. No biological data collected

BMJ Open

RESTORE – Cognitive Functional Therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain: study protocol for a randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031133.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Jul-2019
Complete List of Authors:	Kent, Peter; Curtin University, School of Physiotherapy and Exercise Science; University of Southern Denmark, Department of Sports Science and Clinical Biomechanics O'Sullivan, P; Curtin University, School of Physiotherapy and Exercise Science Smith, Anne; Curtin University, School of Physiotherapy Haines, Terry; Monash University, Faculty of Medicine, Nursing & Health Science Campbell, Amity; Curtin University, Physiotherapy and Exercise Science McGregor, Alison; Imperial College London, Dept of Surgery and Cancer Hartvigsen, Jan; University of Southern Denmark, Department of Sports Science and Clinical Biomechanics; Nordic Institute of Chiropractic and Clinical Biomechanics O'Sullivan, Kieran; Aspetar Qatar Orthopaedic and Sports Medicine Hospital, Sports Spine Centre Vickery, Alistair; The University of Western Australia, General Practice Caneiro, J.P.; Curtin University, Physiotherapy and Exercise Science Schütze, Robert; Curtin University, School of Physiotherapy and Exercise Science Laird, Robert; Superspine Attwell, Stephanie; Macquarie University, Department of Health Professions Hancock, Mark; Macquarie University, Department of Health Professions
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Health economics
Keywords:	Low back pain, wearable devices, rehabilitation, clinical trial protocol

RESTORE – Cognitive Functional Therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain: study protocol for a randomised controlled trial

Peter Kent, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Peter O'Sullivan, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Anne Smith, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Terry Haines, PhD, School of Primary and Allied Health Care, Monash University, Melbourne, Australia

Amity Campbell, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Alison McGregor, PhD, Department of Surgery & Cancer, Imperial College, London, UK

Jan Hartvigsen, PhD, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark; Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark

Kieran O'Sullivan, PhD, Aspetar Orthopaedic and Sports Medicine Hospital, Doha; School of Allied Health, University of Limerick, Limerick, Ireland

Alistair Vickery, MBBS, University of Western Australia, Perth, Australia

J.P. Caneiro, PhD, School of Physiotherapy and Exercise Science, Curtin University, Perth, Australia

Robert Schutze, PhD, School of Physiotherapy and Exercise Science, Curtin University,
Perth, Australia

Robert Laird, PhD, Superspine, Melbourne, Australia

Stephanie Attwell, PhD, Department of Health Professions, Macquarie University, Sydney, Australia

Mark Hancock, PhD, Department of Health Professions, Macquarie University, Sydney, Australia

Correspondence to: Peter Kent

Contact address: School of Physiotherapy and Exercise Science, Curtin University, Kent Street, Bentley, Western Australia, Australia, 6102
Email address: peter.kent@curtin.edu.au

Word count: 4557

ABSTRACT

Introduction: Low Back Pain (LBP) is the leading cause of disability globally and its costs exceed those of cancer and diabetes combined. Recent evidence suggests that individualised cognitive and movement rehabilitation combined with lifestyle advice (Cognitive Functional Therapy (CFT)) may produce larger and more sustained effects than traditional approaches, and movement sensor biofeedback may enhance outcomes. Therefore, this three-arm randomised controlled trial (RCT) aims to compare the clinical effectiveness and economic efficiency of individualised CFT delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

Methods and analysis: Pragmatic, three-arm, randomised, parallel group, superiority RCT comparing usual care (n=164) with CFT (n=164) and CFT-plus-movement-sensor-biofeedback (n=164). Inclusion criteria include: adults with a current episode of LBP >3 months; sought primary care ≥6 weeks ago for this episode of LBP; average LBP intensity of ≥4 (0-10 scale); at least moderate pain-related interference with work or daily activities. The CFT only and CFT-plus-movement-sensor-biofeedback participants will receive seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks. All participants will be assessed at baseline, 3, 6, 13, 26, 40 and 52 weeks. The primary outcome is pain-related physical activity limitation (Roland Morris Disability Questionnaire). Linear mixed models will be used to assess the effect of treatment on physical activity limitation across all time points, with the primary comparison being a formal test of adjusted mean differences between groups at 13 weeks. For the economic (cost-utility) analysis, the primary outcome of clinical effect will be quality-adjusted life years measured across the 12-month follow up using the EQ-5D-5L.

Ethics and dissemination: Approved by Curtin University Human Research Ethics Committee (HRE2018-0062, 6th Feb 2018). Study findings will be disseminated through publication in peer-reviewed journals and conference presentations.

Trial Registration: Australian and New Zealand Clinical Trials Register: ACTRN12618001396213

Strengths and limitations of this study:

- The first fully powered study comparing Cognitive Functional Therapy to usual care as control
- Three-arm trial to quantify the added contribution of movement sensor biofeedback to Cognitive Functional Therapy
- Evaluation of whether cognitive or movement changes mediate improvements
- Evaluation of economic efficiency in addition to clinical effectiveness
- Full participant and therapist blinding not possible

Keywords

Low back pain, wearable electronic devices, rehabilitation, clinical trial protocol

INTRODUCTION

Globally, low back pain (LBP) carries the greatest burden of disease in terms of years lived with disability[1]. Most people with an episode of LBP improve rapidly, however, many have recurrent pain and some develop chronic LBP (pain lasting >3 months) with high levels of disability[2]. This group of patients is responsible for most of the cost and burden associated with LBP[3]. The resultant societal costs of chronic LBP are enormous, exceeding that of cancer and diabetes combined[4 5], with the majority of these costs being due to loss of work participation and on-going care-seeking. Current care models are failing, with LBP-related disability increasing 45% from 1990 to 2010[6].

LBP guidelines recommend that patients seeking care for LBP are initially offered simple interventions (e.g. advice and self-management strategies) and, if they do not improve quickly, then other interventions such as anti-inflammatory medication, exercise therapy and manual therapies[7]. For those patients who fail to respond to these interventions, care is often rapidly escalated, to more invasive, expensive, and potentially harmful interventions, including opioids[8], injections[9], and surgery[10], which have limited evidence of effectiveness despite carrying substantial risks. Furthermore, these patients frequently undergo expensive imaging, which does not improve outcomes and may actually be detrimental[11]. There is an urgent need for effective 'second line' primary care interventions for those patients who do not improve with early standard management, in order to reduce chronicity and limit the number of people progressing to secondary care.

Exercise approaches are the most widely recommended interventions for patients with chronic disabling LBP[12]. A number of exercise approaches, including graded activity, Pilates

and motor control exercises, have been shown to produce small to moderate effects but with a variable duration of improvements.[13-16] One aspect this has been attributed to is a lack of individualised management of known psychological barriers to recovery and inadequate targeting of exercise to each individual's specific functional movement limitations.

Cognitive Functional Therapy (CFT) was developed as a physiotherapist-led, individualised cognitive and behavioural self-management approach to chronic disabling LBP that helps people to: 1) reconceptualise their pain from a biopsychosocial perspective, while dispelling unhelpful beliefs and identifying new cognitive and behavioral responses to pain, 2) build confidence to engage in functional activities related to their goals through functional movement training and 3) adopt a healthy lifestyle by targeting activity avoidance, poor sleep habits, stress management and dietary advice.[17] A Norwegian study of patients with chronic LBP (N=121), found CFT resulted in large sustained effect sizes (12-month standardised effect sizes from 0.7 to 0.9) compared with guideline-recommended manual therapy and exercise.[18] These findings suggest a large, high quality study is now required.

With advances in technology, movement sensors enable accurate measurement and monitoring of lumbar spine movements outside the research laboratory[19]. Wearable movement sensors enable clinicians to precisely measure movement patterns, postures (functional movements) and their relationship to pain, both in the clinical setting but more importantly, during patients' normal activities (work, rest and play) outside the clinic. In addition, movement sensors could help patients to develop an awareness of how they move and the postures they use during normal activities, where changes to these habituated functional movement behaviors are most important. This technology has the potential to increase the effectiveness of therapies aimed at correcting functional movement behaviours.

A recent pilot RCT (N=112) of patients with chronic LBP showed that individualised rehabilitation, based on addressing functional movement behaviours, combined with biofeedback from wearing wireless movement sensors, resulted in large and sustained clinical improvements compared with guideline-recommended treatment (12-month effect sizes from 0.5 to 1.0).[20]

Therefore, this three-arm RCT aims to compare the clinical effectiveness and economic efficiency of individualised CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

METHODS AND ANALYSIS

The RESTORE study is a pragmatic, three-arm, parallel group, superiority RCT comparing usual care with CFT only and CFT-plus-movement-sensor-biofeedback in patients with chronic LBP (Figure 1). The trial will be conducted in Perth and Sydney, Australia. Curtin University Human Research Ethics Committee approved the study (HRE2018-0062, 6 February 2018) and the trial is registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12618001396213). The protocol follows the SPIRIT recommendations[21].

Participants

We will recruit 492 adult participants who meet these inclusion criteria: a current episode of non-specific LBP lasting more than 3 months (including cases with leg pain); presenting to a primary care clinician at least 6 weeks ago for this episode of LBP; scoring an average LBP intensity of 4 or more on a 0-10 Numerical Rating Scale[22]; and having at least moderate pain-related interference with normal work or daily activities (measured by item 8 of the SF-36)[23]. Patients will be excluded if they have any diagnosed medical conditions that prevent them

from being physically active; have a serious spinal pathology (e.g. fracture, infection, cancer); are pregnant or have given birth within the previous 3 months; have inadequate English to comprehend the study's questionnaires and instructions; have a skin allergy to hypoallergenic band-aid or tape adhesives; or are scheduled for major surgery in the next 3 months. In addition to those inclusion criteria, participants will be informed of the locations of the physiotherapy clinics for the study intervention groups and will only be included in the trial if they are willing to travel for treatment to at least one site delivering either of the possible interventions.

Patient and public involvement

Patients and the Public were not directly involved in the design, recruitment to or conduct of this study. They will be involved in our plans to disseminate the study results to participants and relevant community groups, by assisting in the choice of what information/results to share, and in what format.

Recruitment

Trial participants will be recruited via clinicians (e.g. GPs, physiotherapists, pain clinics, surgeons), or directly from the community (e.g. via print media and social media). Clinicians will conduct a preliminary screening of patients with LBP and inform potential trial participants about the study. Those patients who request further information about the study will be provided with a flyer, which directs them to the study website (https://www.restorebackpain.com/) where greater study details, including the participant information sheet and consent form, are provided. Potential participants can opt to have the research team contact them or can simply take the study flyer and contact the research team directly.

Participants will also be recruited directly from the community, without a health practitioner referral. Information about the trial will be disseminated via social media (including Facebook, LinkedIn, Twitter etc.) and print media (including flyers, newsletters, etc.) which will direct to the website and the research team.

All potential participants will be screened for eligibility over the phone by a researcher prior to inclusion. The researcher will also note in the trial database any reasons for excluding a referred patient but not any identifying details of that person. Recruitment into RESTORE commenced on 23 October 2018.

Consent process

Consent will be sought from potential participants who meet the inclusion criteria. A researcher will discuss the trial protocol and offer participants the opportunity to provide consent electronically or by mail (Appendix 1). Electronic consent for the trial will be via a weblink to an electronic version of the consent form. The consent form also asks patients to indicate whether they are comfortable or not with videos being taken of some treatment sessions. Videos are used to monitor fidelity of the physiotherapist in delivering the individualised rehabilitation as per the study protocol. Participants can withdraw for any reason at any time.

All recruited patients will be asked to provide consent for access to their Medicare and Pharmaceutical Benefits Scheme records for the 12-month time period that they are involved in the study. These data will be only used for the analysis of economic efficiency. A paper version of the Federal Department of Human Services-supplied consent form will be sent to

participants for signing and returning via a postage-paid envelope. Declining this consent will not affect eligibility to participate in the clinical effectiveness component of the trial.

Baseline assessment

Following informed consent, participants will self-complete the baseline assessment, including patient demographics and outcome measures, via the online database. A researcher will be available by phone if they require assistance. A detailed description of the baseline variables is provided in Table 1.

Randomisation

After completing the baseline assessment, dynamic (adaptive) random allocation will be used to randomise participants to treatment groups. Randomisation using a 1:1:1 allocation ratio will be conducted by a research assistant by phoning the NHMRC Clinical Trials Centre (24-hour phone service), thereby ensuring concealment of treatment allocation. The NHMRC Clinical Trials Centre will be blinded to baseline assessment. After randomisation and only for those randomised to the CFT-only and CFT-plus-movement-sensor-biofeedback groups, a research assistant will make an appointment for them with a study clinician at an accessible location in their city.

Study treatment

Group 1: Usual care

This treatment will be the usual care pathway the participant's health providers recommend and/or the participant chooses. Treatment in this group will not be impacted in any way by participation in the study. Participants in this group only will be paid a token reimbursement for their time completing follow-up questionnaires (AU$30 for the 3-month questionnaire,

$30 for the 12-month questionnaire and an additional $50 if they complete all the six follow-up questionnaires (3 and 6 week, 3, 6, 9 and 12 month).

Commonalities across the two CFT treatment groups (Groups 2 and 3)

Both CFT treatment groups will have the same treatment frequency of seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks (initial consultation 60 minutes, follow ups 30-40 minutes), in physiotherapy clinics. In both groups, clinicians will use a structured approach to address the relevant cognitive, emotional and behavioural (functional and lifestyle) factors deemed relevant to the individual's presentation[17].

Based on prior screening (Orebro Musculoskeletal Pain Questionnaire and the Patient-Specific Functional Scale) combined with a comprehensive interview and functional examination, the clinician will identify the multidimensional contributors to pain, distress and disability. This will enable the physiotherapist to design a management plan that is tailored to the person's unique clinical presentation and context.

There are three broad components to the intervention:

Making sense of pain: a reflective process that combines the person's own narrative (interview) and experience (during guided behavioural experiments) to develop a personally-relevant, multidimensional understanding of pain for the patient. In this process, unhelpful beliefs and responses to pain are disconfirmed, and new helpful cognitive and behavioural responses (functional and lifestyle) to pain are identified that are linked to their personally relevant goals[17].

Exposure with 'control': a process of behavioural change through experiential learning

following a 'graded exposure' model, designed to challenge expectations of pain and damage consequences via guided behavioural experiments. Specifically, sympathetic nervous system responses (rapid upper chest breathing and body tension) and safety-seeking behaviours (protective muscle guarding, breath-holding, movement avoidance and propping of the hand) that manifest during exposure to painful, feared or avoided functional tasks are explicitly targeted and controlled. This provides patients with strategies to relax, control respiration, normalise postural and movement behaviours that they nominate as painful, feared or avoided. The new strategies are immediately integrated into goal orientated daily activities to build self-efficacy and body conditioning.

Lifestyle change: behavioural modification addressing unhelpful lifestyle factors aimed at increasing physical activity levels based on preference, sleep habits, regulation of stress (via relaxation techniques) and/or dietary advice, where relevant.

CFT is underpinned by a strong therapeutic alliance and motivational interviewing style (open, non-judgmental, reflective)[17] providing validation and facilitating disclosure[24 25]. An individualised progressive self-management program will be provided, monitored and progressed that includes cognitive restructuring, progressive functional exercises and lifestyle changes, tailored to the individual's goals.

All participants in the CFT-only and CFT-plus-movement-sensor-biofeedback groups will wear the movement sensors for the same duration and frequency, but for the CFT-only group, the movement sensors will be a placebo, meaning that the sensors will collect data but neither the patient nor the clinician will have access to it (only the researchers have access). The ViMove2 device (DorsaVi P/L, Melbourne, Australia) consists of miniaturised sensors

attached to the lumbar spine with hypoallergenic tape, and communicate wirelessly with a tablet or mobile phone (Figure 2). At all treatment sessions, patients in both CFT groups will perform forward bending in standing and two other clinically-relevant functional movements selected by the physiotherapist based in the patient specific functional scale. All three movements will be repeated three times and data recorded via the movement sensors.

Differences across the two CFT treatment groups

Group 2: Cognitive Functional Therapy only (CFT-only)

Clinicians and patients in this group will be blinded to all movement sensor output by a software block that only allows the sensors to be configured/started and for the data to be automatically uploaded to a secure cloud-based server. Participants will be told the device is being used to collect outcome data.

Group 3: CFT-plus-movement-sensor assessment and biofeedback (CFT-plus-movement-sensor-biofeedback)

Clinicians in this group will treat patients with the same CFT approach as in the CFT-only group except that in addition, these clinicians will have access to data measured by the movement sensors and be able to use these data for assessment, movement retraining and providing biofeedback. The identification of clinically relevant functional movement behaviors in this particular treatment group will also be informed by data from the movement sensors that are graphically analysed and displayed by the ViMove2 software (Figure 3).

This additional information could assist in guiding individualised movement retraining incorporating the following strategies. Firstly, 'live assessment' can assist in identifying unusual kinematic parameters or movement patterns.[26] Secondly, 'live training' in the clinic,

allows visual interaction by observing real-time kinematic and EMG on-screen data to facilitate changing functional movement behaviours. Thirdly, using the ViMove2 software, clinicians can program movement sensor biofeedback alerts (audio 'beeps' and messages via a trial-supplied iPhone) that will reinforce key principles from the treatment session while the participant goes about their normal daily activities for the rest of the day. The device will prompt the patient when they 'break a movement rule' that has been programmed for them by the clinician. Individualised movement 'prompts' may be time-based, such as reducing long periods of sitting without getting up and moving, or may be kinematically-based, such as reducing sitting in an excessively upright position.

There is no provision for trial-funded ancillary or post-trial care.

Clinician recruitment and training

Depending on recruitment and training success, approximately 16 physiotherapists (8 in each city) will deliver the interventions at private physiotherapy clinics. Each physiotherapist will deliver only one CFT treatment arm, to prevent learning (contamination) from experience using the movement sensor output being applied to the CFT-only patients. Physiotherapists will be randomised into either the CFT-only group or CFT-plus-movement-sensor-biofeedback group. Up to four additional physiotherapists will be recruited and trained in each city to act as reserves if required. For physiotherapists to be considered for inclusion in the training program, they will need to have: at least 2 years clinical experience post-graduation; experience treating people with chronic LBP; an interest in applying biopsychosocial management principles via CFT; a willingness to use movement sensors clinically; less than 4 days of prior exposure to CFT training; and a willingness to be

observed and videoed for mentoring and feedback purposes while treating a *non-trial* patient with disabling LBP.

The clinician training for both the CFT-only group and CFT-plus-movement-sensor-biofeedback group will consist of three components: (i) clinical workshops including live patient demonstrations and mentoring of the physiotherapists while treating patients, (ii) online resources (e.g. e-book and training videos) and (iii) Facebook private support group pages.

CFT training

Six clinical workshops will be conducted (a two-day workshop every month for 6 months) in each city where both CFT-only and CFT-plus-movement-sensor-biofeedback groups will train together. A final single day workshop will be held for each group separately when clinicians will need to demonstrate a pre-defined level of competency, as evaluated by the CFT and movement sensor clinical trainers using a structured competency check-list, before being eligible to deliver the relevant intervention in the trial. The training workshops will include an initial introductory workshop about CFT with patient involvement, a workshop to build skills regarding communication and behavioural experiments, and four workshops involving observation of each physiotherapist examining and treating people with disabling LBP using CFT. The later four sessions will be observed by the clinical trainers, who will provide personalised feedback using a competency checklist developed for the training. The CFT training will be conducted by physiotherapists (POS and JPC) who developed the CFT approach and have extensive experience using and teaching CFT. Clinical competency will be assessed in a final one-day workshop, or by ongoing videos of patients if required.

Movement sensor training

Because the ViMove2 movement sensors are worn by participants in both CFT groups, all participating clinicians will attend a 2-hour technical workshop on setting up and using the ViMove2 devices. This workshop will focus on sensor placement, how to test they are working and how to troubleshoot technical issues. The training will occur after the 6th training workshop and at least 2 weeks before the final single-day workshop. The clinicians in the CFT-plus-movement-sensor-biofeedback group will attend a second 4-hour workshop on accessing and interpreting the movement data (kinematic and EMG) and programming biofeedback. These movement sensor workshops will be conducted by a physiotherapist (RL) with extensive experience using these movement sensors clinically and teaching clinicians in their use. Personalised mentoring by RL will be available over the phone to each physiotherapist for up to five post-hoc reviews of treatment sessions of trial participants.

Ongoing support for both clinician groups

During the trial, private Facebook pages (one on CFT, one on movement sensors for the CFT-only group and one on movement sensors for the CFT-plus-movement-sensor-biofeedback group) and 3-monthly virtual or face-to-face meetings with a clinical trainer will be provided for both clinician groups separately to provide a forum for the discussion of challenges faced when implementing the intervention or with technical issues related to the sensors. The trainers will contribute to the Facebook discussion and 3-monthly meetings.

Treatment fidelity checking

Every seventh participant of each clinician will be selected, and their treatment monitored by the appropriate clinician trainer to ensure ongoing treatment fidelity. If the seventh participant does not consent to this occurring, each subsequent participant of that clinician

will be asked until one consents. This process is recommended in the Spillane (2007)[27] framework for implementation fidelity in trials. This will take the form of video recordings of three consultations (a consultation early in the treatment process, one in the middle and one close to the end of the treatment period) that will be reviewed by a randomly selected clinician trainer (POS, JPC or KOS) with brief feedback provided if required.

Data collection and outcome measures

Data collection will occur at baseline, and at 3, 6, 13, 26, 40 and 52 weeks. Where ever possible, all data will be completed on-line directly into the trial database. Alternatively, patients can complete follow ups over the telephone with a researcher. If participants do not complete follow-ups within 2 day of the scheduled date, they will receive an email reminder and then 2 days later will contacted by one of the study team. Data collected via the ViMove sensors at each clinical visit will be directly uploaded to a database. A detailed description of the data collected at each time point is presented in Table 1.

Primary outcomes

The primary clinical outcome will be pain-related physical activity limitation measured using the Roland Morris Disability Questionnaire[28 29] (RMDQ). For the economic efficiency (cost-utility) analysis, the primary outcome of clinical effect will be quality-adjusted life years calculated using the area under the curve approach based on responses to the EQ-5D-5L questionnaire[30] across each of the assessment time points.

Secondary outcomes

The secondary outcomes include:

- Pain intensity (three numeric rating scales)[31]

- Patient-specific activity limitation (Patient-Specific Functional Scale)[32]
- Pain catastrophisation (Pain Catastrophizing Scale)[33]
- Pain self-efficacy (Pain Self-efficacy Questionnaire)[34]
- Fear of movement (physical activity subscale of the Fear Avoidance Beliefs Questionnaire)[35]
- Patient-perceived global improvement (1 question)[36]
- Patient satisfaction with care and treatment (1 question)[37]
- Adverse events (defined as any morbidity or events causing unwarranted distress to a participant that were potentially related to any trial-related intervention). Clinicians and follow-up questionnaires will inquire about any adverse events.
- Lumbosacral movement will be measured in both CFT treatment groups using ViMove2 wearable wireless sensors and used in the mediation analysis.
- Direct health costs attributable to consumption of health care resources (measured using extracts from Medicare and Pharmaceutical Benefits databases and direct patient reports) and productivity costs (measured using the iMTA Productivity Cost Questionnaire[38]).

Sample size calculation

The sample size was calculated for the primary outcome using the program STATA. A total of 492 patients (164 per group) will be recruited to detect a difference of 2 points (0-24 scale) on the RMDQ between the CFT-only group and CFT-plus-movement-sensor-biofeedback group, $p<0.05$, 80% power, a common standard deviation of 6 points and a worst-case scenario of 20% drop-out rate. Based on our pilot study results[20 39], we hypothesise that the CFT-plus-movement-sensor-biofeedback group would have an average score of 7.5 points on the RMDQ and the Usual care group would have a score of 11.5 points. Pragmatically and arbitrarily, we assume the CFT-only group will have a mean outcome that is half-way (9.5)

between the other two groups and so we will power the trial to detect this as the smallest likely between-group difference (11.5-9.5=2.0).

Blinding

Patients will not be informed of any anticipated results of the trial and will be told that the trial is comparing usual care to two evidence-based interventions. All outcome measures will be either self-reported by patients via web-based questionnaires or collected via the movement sensors or MBS/PBS registers. Unblinded clinicians will deliver only type of one treatment and play no role in collecting data, other than performing a standardised movement protocol with the resultant movement data being automatically uploaded by the sensors to a server without clinician input. Statisticians will be blind to groups.

Statistical analysis

Almost all participant-reported data will be entered directly into an electronic database, where range values are automatically checked. In addition, all data will be checked for range values and outliers prior to analysis.

Treatment efficacy analysis

Repeated-measure linear mixed models will be used to assess the effect of treatment on pain-related physical activity limitation across all time points (3, 6, 13, 26, 40 and 52 weeks), with the primary comparison being a formal test of adjusted mean differences between groups at 13 weeks using intention-to-treat principles. Appropriate sensitivity analyses will be performed on multiple imputed datasets. Estimates of treatment effect will be adjusted for baseline scores of symptom duration, pain intensity, activity limitation (RMDQ score), treatment expectations and significant clinician cluster effects.

The secondary outcome measures will be evaluated using the equivalent repeated-measure linear mixed models.

As widely recommended, we will focus on reporting the size of the effect and its uncertainty (including describing compatibility intervals and p-values) rather than making judgements based on an arbitrary p-value threshold[40-42]. In the papers that report the outcomes of this clinical trial, effect sizes will be discussed relative to those obtained by other interventions in comparable populations.

Analysis of economic efficiency

Direct healthcare and indirect (productivity) costs incurred by participants will be measured over the 12-month follow-up period. Direct health costs will be collected using Medicare Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS) database extractions, and patient questionnaires to capture other health care costs (e.g. hospitalisations). Indirect health costs (e.g. travel to appointments) and productivity costs (including absenteeism and presenteeism) will also be captured in the 3-monthly patient questionnaires. Productivity costs will be measured using the 'iMTA Productivity Cost Questionnaire'. Productivity costs measured at specific time points will be extrapolated to the full one-year period using an area under the curve approach. All costs will be calculated using a 2019-2020 financial base year. Hospital costs will be valued using the National Weighted Activity Unit calculators for the 2019-2020 year.

An incremental cost-utility analysis will calculate the difference in costs between intervention and control groups divided by the difference in quality-adjusted life years. Incremental cost-utility analyses will be undertaken from societal (primary analysis) and health service

(secondary analysis) perspectives. There will also be analyses undertaken for valuation of productivity costs using human capital (primary analysis) and friction (secondary analysis) methods. Bootstrap resampling (2000 replications of original sample size) will be used to generate a 95% confidence ellipse surrounding the incremental cost-utility estimate. Cost-effectiveness acceptability curve analyses will be undertaken if the intervention is not found to dominate the control condition.

Moderation analysis

To investigate if treatment effect is moderated by cognitive flexibility, baseline activity limitation, baseline pain, catastrophisation or self-efficacy (all groups), the interaction term between the potential moderator and the treatment group variable will be assessed in the repeated-measure linear mixed models for pain-related activity limitation and pain intensity described above. Only in the CFT groups, similar moderation analysis will also occur using the STaRT MSK Tool[43 44] (measured at baseline), therapeutic alliance[45] (measured at 3 weeks) and participant-rated adherence to the treatment program measured at weeks 3, 6 and 12 with a study-specific single question ('How would you rate your adherence to the treatment program your physiotherapist has recommended?' 0-10 no adherence to complete adherence).

Mediation analysis

To investigate whether improvement in patients' activity limitation was mediated by correction of habituated functional movement behaviors, or changing patient's pain-related cognitions and emotions, a multilevel structural equation model framework will be utilised. Investigation of the mediation roles of cognitions and emotions will occur using data from all patients; whereas, investigation of the mediation roles of change in movement will occur

using data from only patients in the CFT groups. Results will be expressed as standardised estimates of mediated treatment effect with bootstrapped 95% confidence intervals.

Monitoring:

Because this is not a drug trial and the funder has no access to the data, a data monitoring committee will not be formed and there is no planned trial audit. This does not preclude the administering institution choosing to conduct an audit. There will be no interim analysis and, due to the very low risk of harm, there are no stopping guidelines.

Ethics and dissemination:

This study will be conducted in accordance with the Therapeutic Goods Administration's Note for Guidance on Good Clinical Practice, the NHMRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

Authorship will be based on the Vancouver Convention[46] and no professional writers will be involved.

Any protocol amendments will be detailed in the trial registration (ACTRN12618001396213).

Metadata and appropriate copies of publications will be deposited in the Curtin University eSpace, which is an open access digital repository.

Results will be disseminated via publications in peer-reviewed scientific journals, popular press articles, social media and presentations to scientific and general public audiences.

Data sharing

De-identified data and statistical code will be made available on request soon after each report of the data has been published. Different aspects of the data will be published separately, which will determine when those data are publicly available. A data-sharing agreement will require a commitment to using the data only for specified research purposes, to securing the data appropriately and to destroying the data after a nominated period.

Acknowledgments

The investigators acknowledge the National Health & Medical Research Council (grant number 1145271).

References

1. Hoy D, March L, Brooks P, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. 2014;73(6):968-74. doi: 10.1136/annrheumdis-2013-204428
2. Kongsted A, Kent P, Axen I, et al. What have we learned from ten years of trajectory research in low back pain? *BMC Musculoskelet Disord* 2016(17:220) doi: DOI 10.1186/s12891-016-1071-2
3. Shelerud RA. Epidemiology of occupational low back pain. *Clin Occup Environ Med* 2006;5(3):501-28.
4. Institute of Medicine Committee on Advancing Pain Research C, Education. The National Academies Collection: Reports funded by National Institutes of Health. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US) National Academy of Sciences. 2011.
5. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Arch Phys Med Rehabil* 2014;95(5):986-95.e1. doi: 10.1016/j.apmr.2013.10.032
6. Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380(9859):2224-60. doi: 10.1016/s0140-6736(12)61766-8
7. Wong JJ, Cote P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. *Eur J Pain* 2017;21(2):201-16. doi: 10.1002/ejp.931
8. Deyo RA, Von Korff M, Duhrkoop D. Opioids for low back pain. *BMJ* 2015;350:g6380. doi: 10.1136/bmj.g6380
9. Staal JB, de Bie RA, de Vet HC, et al. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. *Spine* 2009;34(1):49-59. doi: 10.1097/BRS.0b013e3181909558
10. Fritzell P, Hagg O, Nordwall A. Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish Lumbar Spine Study Group. *Eur Spine J* 2003;12(2):178-89. doi: 10.1007/s00586-002-0493-8
11. Webster BS, Choi Y, Bauer AZ, et al. The cascade of medical services and associated longitudinal costs due to nonadherent magnetic resonance imaging for low back pain. *Spine* 2014;39(17):1433-40. doi: 10.1097/brs.0000000000000408
12. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Int Med* 2017 doi: 10.7326/m16-2367
13. Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018
14. Yamato TP, Maher CG, Saragiotto BT, et al. Pilates for low back pain. *Cochrane Database Syst Rev* 2015(7):CD010265. doi: 10.1002/14651858.CD010265.pub2

15. Saragiotto BT, Maher CG, Yamato TP, et al. Motor control exercise for chronic non-specific low-back pain. *Cochrane Database Syst Rev* 2016(1):Cd012004. doi: 10.1002/14651858.Cd012004
16. van der Giessen RN, Speksnijder CM, Helders PJ. The effectiveness of graded activity in patients with non-specific low-back pain: a systematic review. *Disabil Rehabil* 2012;34(13):1070-6. doi: 10.3109/09638288.2011.631682
17. O'Sullivan PB, Caneiro J, O'Keeffe M, et al. Cognitive functional therapy: an integrated behavioral approach for the targeted management of disabling low back pain. *Phys Ther* 2018;98(5):408-23.
18. Vibe Fersum K, O'Sullivan P, Skouen JS, et al. Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: A randomized controlled trial. *Eur J Pain* 2013;17(6):916-28. doi: 10.1002/j.1532-2149.2012.00252.x.
19. Adams MA, Dolan P. Spine biomechanics. *J Biomech* 2005;38(10):1972-83. doi: 10.1016/j.jbiomech.2005.03.028
20. Kent P, Laird R, Haines T. The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial. *BMC Musculoskelet Disord* 2015;16(1):131.
21. Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Int Med* 2013;158(3):200-7. doi: 10.7326/0003-4819-158-3-201302050-00583
22. Manniche C, Asmussen K, Lauritsen B, et al. Low Back Pain Rating scale: validation of a tool for assessment of low back pain. *Pain* 1994;57(3):317-26.
23. Medical Outcomes Trust. SF-36 health survey scoring manual for English language applications: Australia/New Zealand, Canada, United Kingdom. Boston: Medical Outcomes Trust, 1994.
24. Linton SJ. Intricacies of good communication in the context of pain: does validation reinforce disclosure? *Pain* 2015;156(2):199-200. doi: 10.1097/01.j.pain.0000460297.25831.67
25. Edmond SN, Keefe FJ. Validating pain communication: current state of the science. *Pain* 2015;156(2):215-9. doi: 10.1097/01.j.pain.0000460301.18207.c2
26. Laird RA, Keating JL, Kent P. Subgroups of lumbo-pelvic flexion kinematics are present in people with and without persistent low back pain. *BMC Musculoskelet Disord* 2018;19(1):309. doi: 10.1186/s12891-018-2233-1
27. Spillane V, Byrne MC, Byrne M, et al. Monitoring treatment fidelity in a randomized controlled trial of a complex intervention. *J Adv Nurs* 2007;60(3):343-52. doi: 10.1111/j.1365-2648.2007.04386.x
28. Lauridsen HH, Hartvigsen J, Manniche C, et al. Responsiveness and minimal clinically important difference for pain and disability instruments in low back pain patients. *BMC Musculoskelet Disord* 2006;7:82. doi: 10.1186/1471-2474-7-82 [published Online First: 2006/10/27]
29. Patrick D, Deyo R, Atlas S, et al. Assessing health related quality of life in patients with sciatica. *Spine* 1995;20(17):1899-908.
30. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
31. Ross R, ., LaStayo P, editors. *Clinical Assessment of Pain*. Philadelphia: WB Saunders Co, 1997.

32. Hall AM, Maher CG, Latimer J, et al. The patient-specific functional scale is more responsive than the Roland Morris disability questionnaire when activity limitation is low. *Eur Spine J* 2011;20(1):79-86. doi: 10.1007/s00586-010-1521-8
33. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. *Psychol Assess* 1995;7(4):524.
34. Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *EurJ Pain* 2007;11(2):153-63.
35. Waddell G, Newton M, Henderson I, et al. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52(2):157-68.
36. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009;17(3):163-70.
37. Foster NE, Thomas E, Hill JC, et al. The relationship between patient and practitioner expectations and preferences and clinical outcomes in a trial of exercise and acupuncture for knee osteoarthritis. *Euro J Pain* 2010;14(4):402-9. doi: 10.1016/j.ejpain.2009.06.010
38. Bouwmans C, Krol M, Severens H, et al. The iMTA Productivity Cost Questionnaire: A Standardized Instrument for Measuring and Valuing Health-Related Productivity Losses. *Value Health* 2015;18(6):753-8. doi: 10.1016/j.jval.2015.05.009
39. Vibe Fersum K, O'Sullivan P, Skouen J, et al. Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: A randomized controlled trial. *Eur J Pain* 2013;17(6):916-28.
40. Editorial: Moving to a World Beyond "p < 0.05". *The American Statistician* 2019;73:1–19.
41. R.L. W, Lazar NA. The ASA's Statement on p-Values: Context, Process, and Purpose. *The American Statistician* 2016;70:2:129-33.
42. Herbert R. Research Note: Significance testing and hypothesis testing: meaningless, misleading and mostly unnecessary. *Journal of Physiotherapy* 2019;65:178–81.
43. Campbell P, Hill JC, Protheroe J, et al. Keele Aches and Pains Study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. *J Pain Res* 2016;9:807-18. doi: 10.2147/jpr.S116614
44. Dunn KM, Campbell P, Afolabi EK, et al. 176. Refinement and validation of the Keele STarT MSK Tool for musculoskeletal pain in primary care. *Rheumatology* 2017;56(suppl_2)
45. Hall AM, Ferreira ML, Clemson L, et al. Assessment of the therapeutic alliance in physical rehabilitation: a RASCH analysis. *Disabil Rehab* 2012;34(3):257-66.
46. International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors [Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html accessed 21 February 2019.
47. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8(2):141-4.
48. Stratford P, Gill C, Westaway M, et al. Assessing disability and change on individual patients: a report of a patient specific measure. *Physiother Can* 1995;47(4):258-63.
49. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20(10):1727-36.
50. Rofail D, Myers L, Froggatt D. Treatment Satisfaction and Dissatisfaction in Chronic Low Back Pain: a Systematic Review. *J Psychol Psychother* 2016;6:260.

51. Martin MM, Rubin RB. A new measure of cognitive flexibility. *Psychol Rep* 1995;76(2):623-26.
52. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009;17(3):163-70.
53. Larsen DL, Attkisson CC, Hargreaves WA, et al. Assessment of client/patient satisfaction: development of a general scale. *Eval Prog Plann* 1979;2(3):197-207.
54. Bouwmans C, Krol M, Severens H, et al. The iMTA productivity cost questionnaire: a standardized instrument for measuring and valuing health-related productivity losses. *Value Health* 2015;18(6):753-58.
55. World Health Organization. International ethical guidelines for health-related research involving humans: Geneva: Council for International Organizations of Medical Sciences 2016.

Authors' contributions:

PK and MH wrote the initial draft manuscript. All authors (PK, POS, AS, TH, AC, AM, JH, KOS, AV, JPC, RS, RL, SA and MH), contributed to and revised subsequent drafts and approved the final version.

Funding statement:

This work is supported by National Health and Research Council (www.nhmrc.gov.au) grant number APP1145271, however the Council has no role in study design, data collection, management, analysis, and interpretation of data, writing of reports and the decision to submit any report for publication. The trial team will have unrestricted access to the final trial dataset.

Competing interests statement:

JPC, KOS and POS deliver continuing education workshops on Cognitive Functional Therapy, for which they receive honoraria. The authors declare no other competing interests.

Figure legends:

Figure 1: Flow chart

Figure 2: Placement of the ViMove2 movement sensors

Figure 3: Example movement data (flexion) graphically analysed and displayed by the ViMove2 software

Protocol version:

Version 1, 12 April 2019

Table 1: Trial data collected and their purpose

Construct	**Measure**	**Time points (weeks)**	**Purpose**
Age	Date of birth	0	Describe population
Sex	Male/Female	0	Describe population
Duration of episode	Weeks	0	Describe population
Duration since care-seeking	Weeks	0	Describe population
Previous lifetime episodes	Number	0	Describe population
Height	Centimeters	0	Describe population
Weight	Kilograms	0	Describe population
Education	Categorical	0	Describe population
Current role	Categorical	0	Describe population
Employed	Yes/No	0	Describe population and analysis of economic efficiency
Occupation	Open text	0	Describe population and analysis of economic efficiency
Hours working	Hours	0	Describe population and analysis of economic efficiency
Days working	Days	0	Describe population and analysis of economic efficiency
Sick leave last 3/12	Yes/No	0, 12, 26, 40 and 52	Describe population and analysis of economic efficiency
Days of sick leave 3/12	Days	0, 12, 26, 40 and 52	Describe population and analysis of economic efficiency
Pain-related physical activity limitation	Roland Morris Disability Questionnaire[47]	0, 3, 6, 12, 26, 40 and 52	Describe population, primary outcome, analysis of economic efficiency

Functional limitation	Patient-Specific Functional Scale[48]	0, 3, 6, 12, 26, 40 and 52	Secondary outcome
Pain intensity	Numeric Pain Rating Scales[31]	0, 3, 6, 12, 26, 40 and 52	Describe population, secondary outcome
Fear avoidance beliefs	Fear Avoidance Beliefs Questionnaire (physical activity sub-scale)[35]	0, 12, 26, 40 and 52	Describe population, secondary outcome, mediator
Analgaesic use	Participant self-report text box	0	Describe population, secondary outcome (when matched to 12-month Pharmaceutical Benefits Scheme data)
Catastrophising	Pain Catastrophizing Scale[33]	0, 3, 6, 12, 26, 40 and 52	Describe population, secondary outcome, mediator and moderator
Pain self-efficacy	Pain Self-efficacy Questionnaire[34]	0, 3, 6, 13, 26, 40 and 52	Describe population, secondary outcome, mediator and moderator
Quality-adjusted life years	EuroQOL EQ-5D-5L[49]	0, 12, 26, 40 and 52	Analysis of economic efficiency outcome
Treatment expectations	A tailored question, based on Rofail, Myers and Froggatt 2016[50]	0 (post-randomisation)	Clinical effectiveness baseline covariate
Confidence in intervention	A tailored question, based on Rofail, Myers and Froggatt 2016[50]	3 (CFT groups only)	Mediator
Cognitive flexibility	Cognitive Flexibility Inventory[51]	0	Moderator
Therapeutic alliance	Working Alliance/ Theory of Change Inventory[45]	3 (CFT groups only)	Moderator
Risk stratification	STarT MSK Tool[44]	0	Moderator
Patient-perceived global improvement	Tailored question, based on Kamper et. al. 2009 recommendations[52]	12, 26, 40 and 52	Secondary outcome
Satisfaction with care and treatment	Tailored question, based on Client Satisfaction Questionnaire[53]	12	Secondary outcome

Productivity costs	iMTA Productivity Cost Questionnaire[54] (iPCQ)	12, 26, 40 and 52	Analysis of economic efficiency
Direct health costs attributable to consumption of health care resources	Extracts from Medicare and Pharmaceutical Benefits Scheme databases and direct patient report	12, 26, 40 and 52	Analysis of economic efficiency
Functional movement	Wearable wireless sensors (DorsaVi P/L)	Every consultation (CFT groups only)	Mediator
Adverse events	Tailored question, based on recommendations of the CIOMS Working Group VI[55]	3, 6, 12, 26, 40, 52 and every consultation	Monitoring adverse events

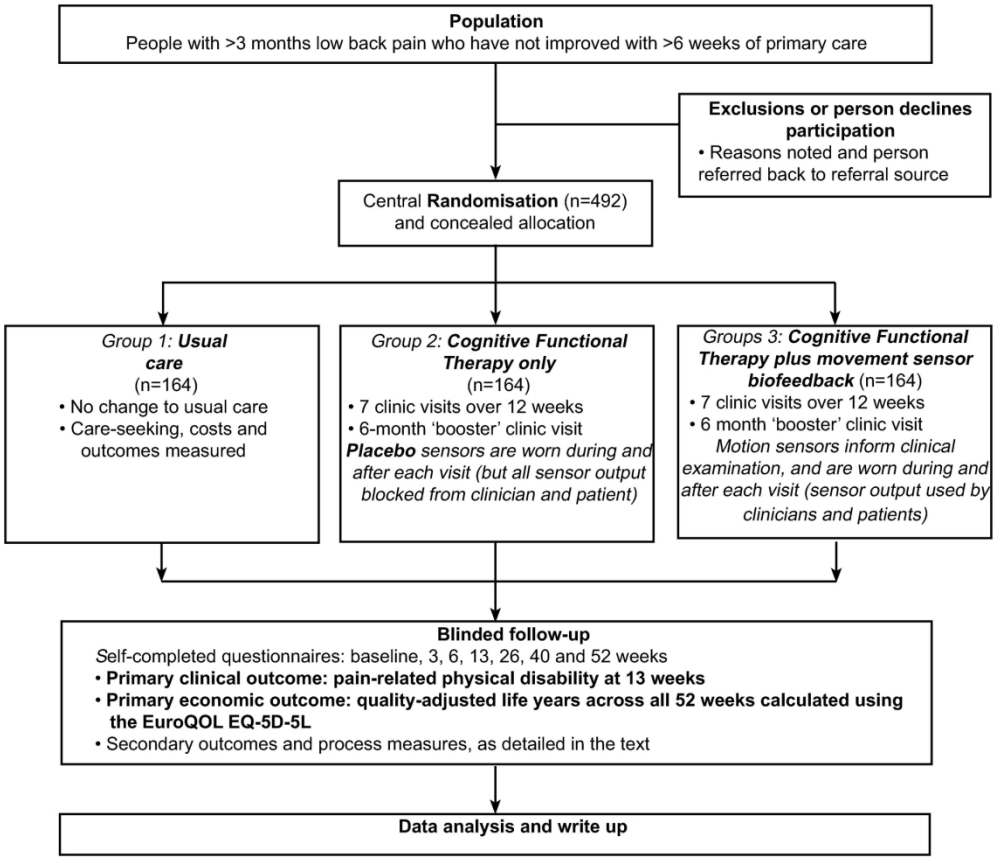
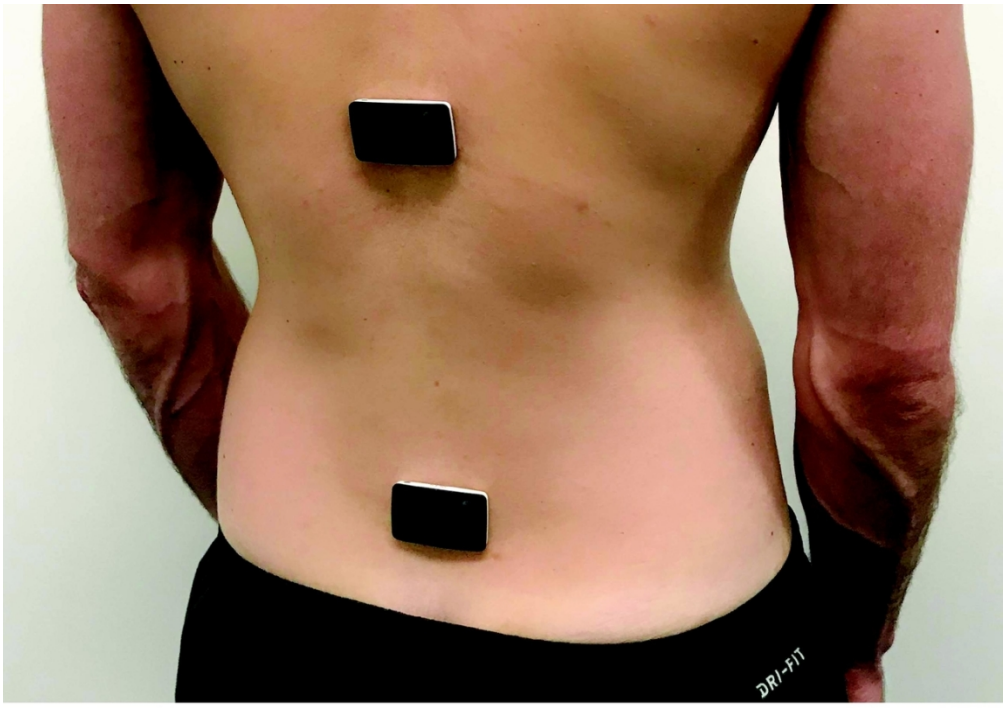


Figure 1: Flow chart

173x154mm (300 x 300 DPI)



Hypoallergenic over-wraps are applied when used during normal daily activities. When EMG sensors are included, they are placed paraspinally at the L3 level.

Figure 2: Placement of the ViMove2 movement sensors

109x91mm (300 x 300 DPI)

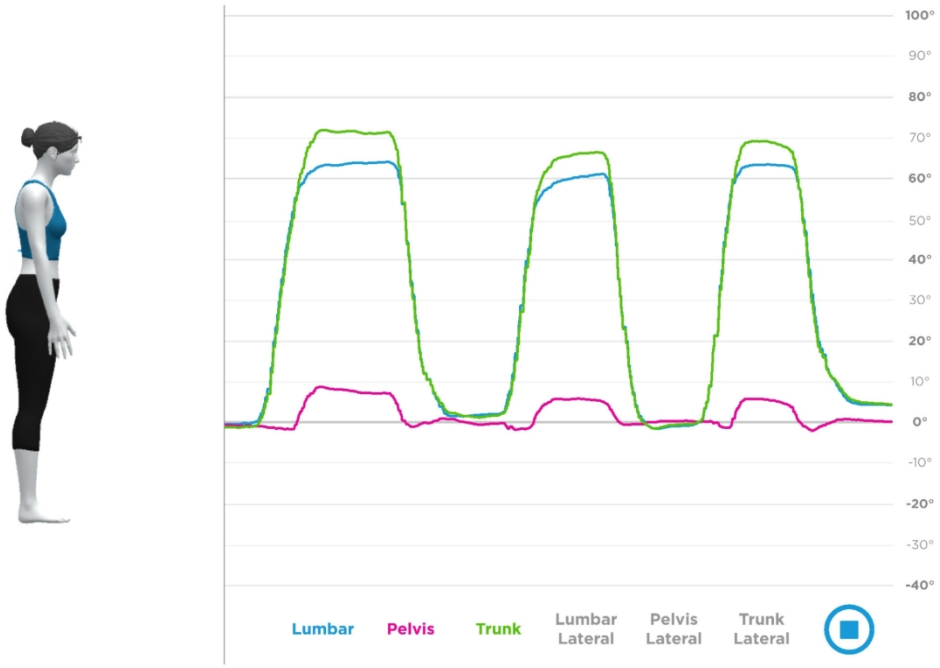


Figure 3: Example movement data (flexion) graphically analysed and displayed by the ViMove2 software

175x119mm (300 x 300 DPI)

Appendix 1: Consent form (paper version)

RESTORE clinical trial

CONSENT FORM

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2018-0062). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au

HREC Project Number	
Project Title	'RESTORE - Individualised movement rehabilitation for chronic, disabling low back pain'
Principal Investigator	Associate Professor Peter Kent, PhD
Version Number	Version 7
Version Date	22 November 2018

- I have read the Participant Information Sheet and I understand its contents
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project and I know I can refuse or withdraw at any time.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – updated May 2015.
- I consent to the storage and use of my information in future ethically-approved research projects.
- If I have been advised not to exercise, I consent to having a Research Assistant contact my GP to clarify whether participating in this project will be appropriate for me.
- If I am receiving third-party compensation due to my low back pain, I consent to having a Research Assistant contact my case manager to clarify whether participating in this project will be appropriate for me.
- I understand that I will receive a copy of this Consent Form and the Participant Information Sheet.
- I understand that if I am in one of the individualised rehabilitation groups, there is a random 1 in 7 chance that three of my treatment sessions might be selected to be potentially videoed. The purpose is to ensure that my physiotherapist is delivering the individualised rehabilitation in the ideal way. If I am selected, I do / do not give permission (please tick the preferred answer) for up to three of my treatment sessions being videoed for that purpose, understanding that I may participate in the trial regardless of the way I answer this:
  - Yes, I give permission ☐ No, I do not give permission ☐
- I understand that I have the option of consenting to the use of my Medicare / Pharmaceutical Benefits data for the 12 months period of my involvement in the trial and that if I agree to this option, I will be mailed a consent form for my signature. I tick my preferred answer below, understanding that I may participate in the trial regardless of the way I answer this:
  - Yes, I will give permission ☐ No, I will not give permission ☐
  - If yes, please provide a postal address to which we can post the consent form:

Participant Name	
Participant Signature	
Date	

RESTORE clinical trial

Declaration by researcher: I have supplied a Participant Information Sheet and Consent Form to the participant who has signed above, and believe they understand the purpose, extent and possible risks of their involvement in this project.

Researcher Name	
Researcher Signature	
Date	

Reporting checklist for protocol of a clinical trial.

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	P4
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	Throughout manuscript
Protocol version	#3	Date and version identifier	P28
Funding	#4	Sources and types of financial, material, and other support	P28
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	P28
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	P28
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	P28
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or	P21

		groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	P5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	P6
Objectives	#7	Specific objectives or hypotheses	P6, P7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	P7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P8, P11
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P7, P8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P10-14
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	P9

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	P17
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P17, Table 1
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, Table 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P18
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	P8, P9
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate	P10

		document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P10
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P19
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Allocation is not blinded to trial staff
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P17, Table 1
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P17

Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P19
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P19
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P21
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P19
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P21
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	P22
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P31

Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	P21
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P7
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	P22
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Appendix 1
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P22
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	P28
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	P28

Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	P14. No provision for compensation, as this type of physiotherapy is a very low risk intervention.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P22
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	P22
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P22
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 1
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a. No biological data collected